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[COMMITTEE PRINT]

RISK: ASSESSMENT, ACCEPTABILITY AND MANAGEMENT

PROCEEDINGS OF A SEMINAR

REPORT

PREPARED BY THE

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FOR THE

SUBCOMMITTEE ON
SCIENCE, RESEARCH AND TECHNOLOGY

TRANSMITTED TO THE

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*On assignment to Budget Committee for 97th Congress.

LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, D.C., November 23, 1981.

Hon. DON FUQUA,
Chairman, Committee on Science and Technology,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Over the last several years the Subcommittee on Science, Research and Technology has taken a strong interest in the development and application of risk assessment. This is a developing science in itself, which is also important in decision-making in many other technical areas.

As part of our activities we have held several hearings on legislation aimed at improving the way risk analysis is used in regulatory law, and we have conducted seminars and joint oversight hearings with interested groups outside the Congress.

The present report covers a two-day seminar conducted by the Congressional Research Service in October of 1980 and entitled "Risk: Assessment, Acceptability, and Management". It contains a thoughtful discussion of many important aspects of Risk Analysis, and I am glad to make it available to a wider audience including members of the Committee on Science and Technology, our colleagues in the House, and interested members of the public.

Sincerely yours,

DOUG WALGREN,
Chairman, Subcommittee on Science,
Research and Technology.

LETTER OF SUBMITTAL

JULY 21, 1980.

Hon. DOUG WALGREN,
Chairman, Subcommittee on Science, Research, and Technology, Committee on Science and Technology, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I am pleased to forward these proceedings of the CRS seminar on "Risk: Assessment, Acceptability, and Management" held October 22 and 23, 1980, which have been transcribed at your request.

The subject of risk assessment is important in a broad range of issues in which science and technology play a crucial role in policymaking, including energy development, food and drug laws, transportation policy, air and water pollution, occupational safety, and consumer product safety. I am pleased that the Committee on Science and Technology has seen fit to expand the audience of the CRS seminar on this important topic through publication of the proceedings.

The seminar was held in two sessions. The first session addressed problems involved in defining and estimating the hazards of various technological activities and determining bases upon which society can make risk acceptability decisions. The second session examined different mechanisms for implementing risk acceptance decisions.

The seminars were moderated by Dr. Robert Civiak and Mr. Kenneth Bogen of the Science Policy Research Division, who also edited the transcripts of the proceedings. Dr. Gail Marcus, Assistant Chief of Science Policy Division, served as project coordinator for these activities.

Sincerely,

GILBERT GUDE, *Director.*

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RISK: ASSESSMENT, ACCEPTABILITY, AND MANAGEMENT

Congressional Research Service Seminar

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Analyst in Life Sciences
Science Policy Research Division
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October, 1980

RISK: ASSESSMENT, ACCEPTABILITY, AND MANAGEMENT

Congressional Research Service Seminar

Whittall Pavilion

The Library of Congress

Wednesday, October 22, 1980

GILBERT GUDE: I want to bid you a good morning. I'm Gilbert Gude, Director of the Congressional Research Service, and I'd like to welcome you to the Library of Congress and, more specifically, the Whithall Pavilion where we endeavor to maintain what we call a neutral, friendly ambience to get together and discuss the very difficult problems that we have today.

This question of risk assessment, of course, mounts high in that group of difficult problems. We, like a lot of you in your organizations have been involved in various pieces of it--CRS has provided a nuclear versus coal study and some studies in biological experimentation risks. But, in these two morning sessions we are going to, we hope, pull it together and see if we can get a broad view of the whole subject area.

We're so pleased to have as our panelists James Vaupel, Marvin Schneiderman, and Sheldon Samuels and appreciate their pitching in. Also our discussants, Douglas MacLean and our own Senior Specialist in Conservation and Energy, Warren Donnelly. I want to thank the Science Policy Division and the people who assisted in putting this together; and, in particular, Bob Civiak, Ken Bogen, and Gail Marcus, who have done yeoman service in doing this. Bob Civiak will be our moderator today. Bob, take over.

ROBERT CIVIAK: Thank you.

GUDE: Thank you for all your good work.

CIVIAK: I'm glad you could all come. I was a little bit worried about the risks of holding a seminar for congressional staff people 2 weeks before an election, but the good turnout shows that that risk was an acceptable risk. I really wasn't too worried because there has been widespread Congressional interest in the topic of risk. I did a search yesterday and there

were 177 bills submitted in the 96th Congress that have the word "risk" in their abstracts. These bills are in such diverse areas as energy development, food and drug laws, transportation policy, air and water pollution, and consumer product safety.

We hope that this seminar will address the subject of risk in a manner which will be relevant to all those different areas. We're going to have two sessions. Tomorrow we'll discuss different mechanisms for controlling risks, such as regulation, compensation schemes, public education, and various other alternatives, but today we're going to discuss the issues which must be considered before you can make risk management decisions. The problems we'll be discussing today are things such as the problems in defining and estimating risks--and those are very formidable problems--and the difficulties in determining acceptable levels of risk.

I think that everybody realizes that a risk-free society is impossible, but politically it's very difficult to condone even a small amount of risk, and I hope our speakers today will address that question. We have a distinguished group of speakers, some of whom have performed risk assessments and others who have studied generic problems in assessing risks. I'm going to introduce all the speakers before we start.

The first speaker is going to be Dr. James Vaupel. He's a Professor of Public Policy Studies at Duke University, and he's also the Study Director of the National Academy of Sciences' Committee on Risk and Decision-making. He's published extensively on the topic of risk, including a recent article with the engaging title of "Eggs in Your Bier".

We were going to have Dr. Richard Wilson who is a member of the NAS Committee, but he isn't going to be able to be here.

The second speaker is going to be Dr. Marvin Schneiderman, who is currentl with Clement Associates. Dr. Schneiderman is a former Director for Science Policy of the National Institutes of Health, and he's an expert in statistical analysis and mathematical statistics.

After he's finished with his talk, he's going to put on his Richard Wilson hat and do about five minutes of what Richard Wilson was going to say--or what he thinks Richard Wilson was going to say.

Our third speaker is Sheldon Samuels. He's the Director of Health, Safety, and Environment of the Industrial Union Department of the AFL-CIO. He's worked for the United States Public Health Service, the New York State Health Department, and the Environmental Protection Agency, and has published extensively regarding the health and social effects of hazards in the workplace and in the community.

We hope we can foster a free exchange of ideas. Each speaker has been asked to keep his remarks to about 15 minutes. Then we're going to have two discussants comment on what they heard and begin the question and answer period. The discussants are Dr. Douglas MacLean, who is a Professor of Philosophy from the University of Maryland and who's currently doing work on the topic of risk and consent, and Warren Donnelly, who is a Senior Specialist in Conservation and Energy from CRS. I'm sure many of you know Warren.

With that we'll begin.

DR. JAMES W. VAUPEL: I've got a little slide show for you. I teach at Duke and I tried it out on my students, and they told me to tone it down a little bit, but that probably it will be alright.

I would like to introduce the topic of risk by trying to put risk in perspective. A lot of my own--this is based on my own research and not necessarily the views of the National Academy. A lot of my own research has been on death and on the prospects for averting death--the prospects for saving lives. When we think about risks it's useful to worry about what are the risks that we face and what are the different kinds of risks we should worry about. What are the big risks we face; what are the smaller risks? Are things getting better or are they getting worse? What are people dying from? What can we do about it? So the basic topic of my talk will be what risks should we be worrying about, and I want to do this from three perspectives.

The reason three perspectives are important is that, depending on how you look at this problem, you feel better or worse about it and, also, you get different hints about what you should be worrying about.

The first perspective I want to talk about is the fact that mortality and morbidity are declining. And I'll talk about that in a minute. Mortality and morbidity have been declining quite rapidly in the United States, and to the extent that the health and safety risk problem is essentially the problem of averting deaths, illnesses, and injuries, we've been doing very well.

The second perspective is that public concern has increased--and I think we should worry about that, and I'll talk breifly about that.

And then, finally, the third perspective I want to take is that there are some big problems that remain and some very large problems that seem to be increasing, and that's where I think we might want to focus some of our attention.

Perspective One. Mortality and morbidity have declined steadily since 1900 and the cumulative effect has been dramatic. Let me give you some brief statistics about this. One set of statistics that is interesting is statistics on life expectancy. In 1904 life expectancy was under 50 years and today it is over 75 years, so there has been a dramatic gain in life expectancy. And that gain in life expectancy, due to the reduction in mortality, has not only occurred at early ages, but has also occurred in old age as well. And there has been a dramatic increase in life expectancy even at age 65.

In 1900 the life expectancy at 65 was only 11 years, and today it is 16 years. That's almost a 50 percent increase. And that gain in life expectancy at age 65 has occurred despite the fact that in 1900 very few people lived to age 65, and now lots of people live to age 65, so there are more frail people around who are 65 years old. Nonetheless, we have dramatically increased their life expectancy.

A second perspective on this comes from the probability of death before age 65, which is something I've written about before--I call it early death. [See figure 1] The vertical axis here is the probability of death before you are 65. The horizontal axis is years--the years, they're a little hard to

read, but they start with 1900 here. The dots represent the probability of death before age 65. In 1900 it was over 60 percent. Today it's a little more than 20 percent. The decline has been about 5 percentage point per decade, and it's been pretty much linear.

During the 60's there was a period of some slowing of progress, but during the 70's there's been rapid progress that's made up for the slow down. If we continue this rate of progress, within 50 years we'll pretty much eliminate the probability of death before 65. If we could speed it up, we might be able to eliminate--virtually eliminate--the probability of death before age 65 in this century. And I personally think that this way of looking at the problem suggests that we ought to try to learn from what we've done in the past to try to see how we can increase the very great progress we have been making.

It might seem incredible to you all that we could virtually eliminate the probability of early death, but let me give you the following statistics: In 1900 the probability of dying during the first year--dying as an infant--was over 20 percent, and now it's down around 1 percent. Today the probability of dying before age 65 is over 20 percent. And why can't we similarly reduce that to under 1 percent? And I think we will. We have been making this steady progress. Let me give you some statistics on the different kinds of progress we've been making.

The main progress has been with infectious diseases. We've pretty much eliminated deaths from the major infectious diseases. If death rates today were the same as they were in 1900, almost a million people would die this year from tuberculosis, gastritis, polio, and diphtheria. This year only 10,000 people are going to die from all four of those diseases put together, so we've saved a million lives a year from those diseases.

We've also made progress--lots of progress--in cardiovascular diseases and nonmotor vehicle accidents. Since 1950 the age-adjusted death rate for cardiovascular diseases has been cut in half; and the death rate for nonmotor vehicle accidents today is only about a quarter of what it was in 1900. So it's very dramatic progress--partially due, I should say, to the work of labor unions

who have dramatically reduced the incidence of occupational accidents. There's two exceptions to this--cancer and motor vehicle accidents. The cancer death rate has been increasing by about 1 percent a year. I think Dr. Schneiderman, who is one of the world's leading experts on this, may address this problem. But it's a complicated problem. One reason it's complicated is that, if you subtract lung cancer deaths due to cigarette smoking, the cancer rates remain mostly level. But it's hard to interpret exactly what that means. Even if that's true, I think it shows that we haven't been doing very well against cancer. We've been dramatically reducing other causes of death, but we haven't been doing very well in reducing cancer deaths. The motor vehicle accidents have also remained relatively level since the Second World War, but since that time, Americans now drive 5 times as much, so that although the death rate is level, the death rate per mile driven has declined by a factor of 5. In addition, most illnesses and injury rates have also declined steadily with dramatic cumulative effect, so we've been doing very well against morbidity as well as mortality.

That's perspective one. Now let me tell you about perspective two. Most Americans believe life is getting more risky. There was a recent Harris poll. The Harris poll indicated that by a margin of 12 to 1, Americans thought life was riskier today than it was 20 years ago and by 3 to 1 they thought that life 20 years from now would be riskier than it is today, so the overwhelming majority of Americans believe that life is getting riskier--and it's a puzzle. Why do Americans think this? And what are the underlying concerns that have given rise to this feeling? Because clearly the fact that Americans believe that life is getting riskier is a very important problem and a very important concern that we should try to understand.

Now, there's certainly been, corresponding to this public opinion, a rising tide of concern and activity, as you know, in Congress and in the Federal agencies, the courts, the media, industry, labor, public interest groups, the National Academy of Sciences, the National Science Foundation, which set up

a new risk assessment group--TARA--and in universities. And, as you all are familiar with, over the last 10 years there's just been this enormous increase in concern and activity about risk. At the same time we've been making this dramatic progress against mortality and morbidity.

Now, one of the things that the National Academy of Sciences' Committee that I'm working with has investigated is, why has public concern about risk increased? And we've come up with a number of hypotheses--I don't know how good they are.

One is that the public feels reduced confidence in its institutions, in particular, reduced confidence in the ability of these institutions to handle risks in a sensible way.

The second hypothesis is that we're getting richer; and as we get richer, we want even more health and safety. Health and safety, to use economist's jargon, is a superior good, and as we get rich we want more health and safety and our expectations are rising even faster than the progress that we could make.

A third possible hypothesis is that we're just much better at identifying risks so that people see or hear about lots of additional risks because we identify them better, even though the mortality and morbidity statistics are going down.

And then another hypothesis here is that people particularly resent man-made risks and risks that are involuntarily imposed on people. That in the past a lot of risks seemed to be from nature, from God--you couldn't do anything about them, but today the risks come from DuPont and that seems particularly obnoxious.

There are a couple of other hypotheses, and that brings me to perspective three. Perspective three is the fact that some big problems are being neglected and some big risks seem to be increasing. That's what I'd like to turn to now.

First of all, what are the big risks that are increasing? I've made a list of four of them that worry me particularly. Nuclear war--I think the risks of nuclear war are increasing. Certainly, nuclear weapons are proliferating,

and the recent Iran-Iraq crisis indicates how little power the United States has anymore in keeping the countries of the world from fighting each other.

The Global 2000 Report that the Council on Environmental Quality and the State Department just issued makes a very pursuasive case that there's increasing global instability--increasing divisions between the Third World and the developed world. All the mortality and morbidity statistics I gave you were from the very narrow perspective of the United States. I think if you stepped back and looked at the risk picture from a world point of view, you'd be much less optimistic about what's happening. In fact, from a world point of view, it seems fairly clear the risks are probably getting worse. Most people of the world are not doing very well.

A third big emerging risk seems to be toxic substances, hazardous wastes, chemical poisoning, nuclear wastes, and so on. And the public is very concerned about this, and there's a lot of evidence to suggest that this may actually be a very big problem.

And then, finally, the National Academy of Sciences and other people have done work on climate change due to the depletion of the ozone layer as well as the greenhouse effect caused by carbon dioxide in the atmosphere. If those predictions are right, and if the earth's climate will warm, leading to melting of the ice caps and an increase in sea level and a change in rain pattern and so on, the next century could see a catastrophic change in weather patterns.

So some very big risks seem to be going up. The Harris poll that asked people about why they thought risks were going up tried to pin down and ask people specific things. Some of the things the Harris poll uncovered were these. That people are very worried about crime. You don't ordinarily think about this as an environmental risk, but people do--when you ask them about it, they think of this.

They also said they thought risks were going up because of unemployment. Once again, it's kind of tangential, but that's what the people were worried about. They were worried about the effects of inflation eroding their income,

and the increasing uncertainty about the future--and in particular, the effect of inflation on poverty, old age, and the possible bankruptcy of the Social Security System. These fears seem to be increasing.

The last thing I want to turn to is what I think are some big, neglected problems that people may be worried about or that people should be worried about from this Perspective Three. I'd like to talk briefly about mortality differentials. Blacks have, at any age up until advanced old age, two to three times the death rate of whites. I personally think this is the biggest inequity in America--that just because you're black, you have two to three times the death rate. The probability of death before age 65 for black males is roughly 50 percent--more than twice the probability for whites.

Similar risks exist for the poor. Victor Fuchs has done some work that suggests that it's not merely the poor but especially the poorly educated--it tends to correlate. People who are poorly educated seem to have two or three times the death risks of middle class whites.

And then probably the most disadvantaged group in American society is the migrant workers. Migrant workers, according to the very limited data that's available, have a life expectancy of under 50 years, which is comparable to the life expectancy of people in the poorest countries of the world. Less than the life expectancy of Mexico, less than the life expectancy of Syria.

So I would think that here are three very, very big opportunities for saving lots of lives. Another possibility for saving lots of lives is that the United States does just terribly compared to other developed countries in terms of the risks of death. One way of seeing this is to rank the United States compared to other countries in terms of the probability of death before age 65. Life expectancy disguises things a little bit. Infant mortality shows it up very well, but life expectancy before 65 also shows it up. I jotted down this little table [table 1] of the probability of death before age 65.

Starting with Sweden we run down the table and U.S. whites are way down here. Then we keep on running down past Austria and Ireland and Northern Ireland

and Malta and Scotland and Hungary and Hongkong, and that's the U.S. total. And then we keep on running down past Trinidad, South Korea, the Bahamas, Malaysia, and Chile. And there we have the U.S. non-whites. The migrant workers fall off the bottom of the table. These are all the countries in the world for which recent mortality data are available, and you can see that the U.S. whites are doing very bad compared to other developed countries, and U.S. non-whites rank with the--their mortality experience ranks with the poorest countries of the world.

Okay. Let me just summarize briefly. I tried to present you with three perspectives on the risks we face, stepping back from the concerns that are in the newspapers today and trying to worry about the broader issues of risk. Perspective one says we have made great progress--that if we continue to make the kind of progress we have made, we may be able to drastically reduce the incidence of mortality and morbidity at early ages, in this century. And that we should try to learn from the progress we have made and try to accelerate that progress.

Perspective two says that people are very concerned about the risks we face. There's eroding confidence in our institutions. The fact that people are concerned is itself a concern. We are worried about that, and we ought to worry hard about what we can do to try to address people's concerns in a meaningful way.

The third perspective I tried to give you was that there are some very big risks out there that seem to be neglected, that we don't worry about enough. There are some catastrophic risks which, if they occur, will completely dwarf all the other risks we face. In fact, if you think about those catastrophic risks, it may very well be true that although mortality and morbidity are going down, the risks we face are going up. I mean, that people may be absolutely right about that. The risks we face may be going up dramatically, even thought mortality and morbidity are going down. What's going to happen is we're all going to get wiped out in a few years?

But in addition to that, there are, I think, some major inequities in our society pertaining to blacks, the poor, migrant workers, and so on, and our society also does very poorly compared to other countries and we ought to try to investigate those problems and do something about those problems.

Now, in conclusion, I testified in May before Congressman George Brown's Subcommittee, on Congressman Ritter's bill on comparative risk analysis, and I'm strongly in support of that bill. I think it's now called H.R. 8303. It seems to me that if you want to do something about risks, if you really want to save lives, you have to do some counting. You have to do some counting of how many lives and limbs can be saved and how well can you do saving lives and limbs here, compared to saving lives and limbs someplace else. Comparative risk analysis basically is no more than a systematic counting of effects. That kind of systematic counting of effects can help uncover problems, like the problems of black and migrant workers, it can help us set priorities so we can address the big risk problems that we face and not the trivial ones; and it can help us gain a better perspective--a perspective or, a set of perspectives--on what the nature of the risks are.

So in concluding, I'd just like to advocate more counting, more estimating, of health and safety effects. That, I think, is what Richard Wilson was going to talk about. But maybe Marvin Schneiderman can follow up on this.

CIVIAK: That probability of death before 65, when is that evaluated?

DR. VAUPEL: Oh, it's at current mortality rates.

CIVIAK: With the current population?

DR. VAUPEL: Yes. Given the current life tables, if a newborn were born today and experienced the mortality rates that we experience today, what the probability would be of death before 65.

CIVIAK: The probability at birth?

DR. VAUPEL: The probability at birth, yes--of death before 65.

CIVIAK: We will now turn to Dr. Marvin Schneiderman.

DR. MARVIN SCHNEIDERMAN: Jim, thank you for that very nice presentation. I learned several things, and that's always good. I'll not talk this time in

terms of specific comments on some of the things that Jim talked about. Perhaps that will come out in the discussion later. I'm going to limit myself to the subject in my title which is, "Are Their Risks to Risk Analysis?" Bob Civiak remarked, when he heard that title, "Any time a title has a question in it, the answer is, 'yes'", and he's absolutely right.

But let me tell you what I think some of the risks are to risk analysis--and having found risks, I will not go on to argue that therefore we should not do risk analysis. There are risks to all of the things we do in our everyday life which does not stop us from doing these things. It may constrain us from doing them at times, however. I don't drive on New Year's Eve if I can help it. It just seems to me that driving is risky itself, and driving on New Year's Eve is even riskier, so I have some constraints. My point is that risk analysis may be risky and, therefore, I may do some risk analyses, but not some others.

What I want to talk about, are the few areas in which we know how to do some risk analysis with respect to specific diseases. The disease that I've worked on most of my adult life is cancer. We know a good deal about how to do some experimentation in cancer; we know a good deal about animal testing in cancer; we've now developed some techniques for quicker and cheaper testing than the animal testing. That leads me to two further things. First, with respect to almost any other chronic disease we don't know how to do the kinds of risk assessment we can do in cancer. There are no decent animal models for heart disease. There are no decent animal models for stroke. There are no decent animal models for most of the other chronic diseases--that we can do this in cancer is because we have supported the research in cancer rather effectively, and risk assessment is one of the things we have learned.

Back in 1961 Nathan Mantel and Ray Bryan, of the National Cancer Institute, wrote a paper, the title of which was something about risks in cancer, and they proposed an idea that has since been taken up recently as if it were a brand new idea. I suppose, considering the generation gap, it is a brand new idea. Their idea was that one ought to look at the problem of a so-called "virtually

safe level" of exposure or risk. Since we can't guarantee a zero risk society, they asked, "What's a virtually safe level of risk in our society, and how can we get to it?" Mantel and Bryan arbitrarily set this risk level at one in a hundred million, and then they said, "Now, how can we achieve that from looking at what we know about the results of testing materials for carcinogenesis in animals?" That's another way of asking, "What's the dose that would produce a risk of one in a hundred million in the lifetime of the C3F mouse?" Most of us are not C3F mice. Thus, while the Mantel-Bryan procedure was the first of the models for extrapolating from a high dose to a low dose in the mouse or in any other experimental animal, it went only part way toward estimating the one in 100 million dose for humans.

Their proposal was attacked early-on as giving far too low a dose. It was said that it gave an unrealistic, impossible of achievement, dose. The Mantel-Bryan procedure is a modified probit analysis model, which relates to variability in the population. Mantel had done some work on the potency estimation of drugs, and that's what led them into this. Bryan had done some work i potency analysis, too.

Having been attacked that theirs was too rigid a procedure which then gave you too low a dose, Mantel and Bryan essentially put their scheme aside and didn't do much more with it. Roughly 10 years later people began working on the problem again, and among the first things they did was to decide that Mantel-Bryan was not too rigid or too tight, but was not rigid enough. It was not rigid enough, they said because it did not really reflect the basic biology of what was going on. It did not reflect, the thinking then, and the current thinking today, that cancer is a disease of multiple stages and multiple origins. Among the things that this multi-stage theory would lead to is that one ought to have, at very low doses, a response that was linear in the dose. The linear dose models, however, gave us even lower, so-called virtually safe doses than did Mantel-Bryan.

Other people looked at the problem in still another way and said, "Well, really, you can't guarantee immortality"--in spite of the curve that Jim showed earlier that the probability of death before 65 is going to reach zero or near zero by 2020. They argued that what we really want to do is to reduce life shortening.

We want to extend life as long as we can. So we want to look now, not to, "yes or no, you're going to die of cancer," because obviously, even if we eliminated all other diseases and we then died of cancer at the average age of 120, from one point of view we would have failed. Cancer deaths would go up from roughly 20 percent of the total to 100 percent of the total. Nonetheless, we would have achieved something. We would have extended the lifespan substantially. So people then began to look at time-to-appearance models. When will the tumors appear? When will the cancer appear? If this could be long delayed, then perhaps life could be extended. Dying of cancer at a later age is better than dying of cancer at a younger age.

Time-to-appearance models had a real flurry, and they led to some concepts of a so-called practical threshold. If the average age of the appearance of the disease would be (if you died of no other causes) 320 years at some low dose, then really, you don't have to worry about the dose. Hardly anybody is going to live to the age of 320. So you don't have to worry about that particular low dose. That dose could be considered a "practical threshold."

The difficulty with this concept was, as Mitchell Gail demonstrated, that a median appearance of the disease at age 320 still implied, because of the wide distribution of the time of appearance of the disease, a fairly substantial death rate at ages below 65, or below 70. So that particular model is still being worked on. It has substantial promise, but it hasn't been fully developed.

There are several other models. . . . I talked about straight line estimation. That's the estimation approach that comes from the one-hit model. In addition, there are multistage models, multihit models, and several others. So in terms of extrapolating from mouse at high doses to mouse at low doses and then

mouse to man, we still have substantial difficulties in determining what is the correct model. One of the risks of risk assessment is that if we're going to use the animal experimentation for risk assessment, we don't really know what risk assessment to make. The different models give you very substantially different answers.

I was looking at this new Volume 3 of Drinking Water and Health which was just published by the National Academy of Sciences. There's a chapter in it called, "Problems of Risk Estimation," Chapter 3, and in that chapter they reproduce a table from a paper from a group working several years ago for the Food and Drug Administration, in which they compared three different models to a set of hypothetical responses. The responses ran from about 2 percent at the lowest dose to about a 98 percent response at the highest dose. The highest dose was 256 times the lowest dose. All three models fitted the data very nicely in the 2 percent to 98 percent response range. Then they said, "given these three different models, if a unit dose produced a 50 percent response, what response would you have with a dose of .0001.?" At a dose one ten-thousandth of the dose that produced the 50 percent response, what would the response be? What estimate do you get from each of these three different models? The range of response that these three different models predict at the same low dose is of the order of about 15,000 fold; this despite the fact that all three models fitted the data very nicely in the range from 2 to 98 percent. Going out there to that lower end of the curve got us that enormous range in estimation. So we have this difficulty now, even if we had these data in humans--somehow or other we had this terrible situation in which we were able to measure these effects in humans, and we had this wide dose response effect from 2 percent to 98 percent--we still don't know what's going to happen at this substantially lower dose; at the levels that are concerning us now. Through just the difference in the models, we get an enormous difference in the estimated risk down at low levels.

Another piece of the problem is that, by and large, for most illnesses--particularly cancer--we have some background level. The background level has to be taken into account. Our aim is to keep excess risks so low that we get close to the background level. This turns out to be an interesting problem--how do I take background level into account in making estimates of excess risk.

If I were to take out background level by saying, for example, if background level of cancer is 2 percent, that means I've only 98 percent to go, and I use the system called Abbott's Correction that's been used in laboratories for years, I get one answer as to what a low dose will give me. This argues, in effect, that all causes operate independently. On the other hand, if I argue that it is an unknown dose that gives me this background, and I just have to add that dose on to the dose of the suspect material, I get a very much higher estimate of what a low dose will produce for me. This second approach assumes that many things can cause the same disease--as they appear to do in cancer--and they do not operate independently. So just a simple, technical question of how one takes into account "background" very much modifies the answer that we get in terms of what risks we estimate, from the animal models.

For the animal studies at least we have some data. We want to use animal models in a general way--we don't want to have human data to use. I, for one, would hope that there would come a time in which we never had any human data. That would imply that humans had never been exposed, so we couldn't have the human data. I'd prefer not to have human data on most carcinogens because humans had not been exposed.

But suppose we do have humans exposed. We then might have human data. We have human data on the asbestos exposure; we have human data on vinyl chloride exposure, and about 20 or 30 similar materials. The difficulty with using the human data is that, by and large, mother nature never read R. A. Fisher's book on the design of experiments. The experiments that mother nature conducts are large, they're awkward, they're unbalanced. If these were brought before any study section at NIH for funding, they'd not be funded, because they're just not well designed.

They're not well designed because humans live in very diverse ways and they're exposed to all kinds of different things and conditions. Some of them smoke; some of them drink; some of them both drink and smoke;--so that the data that you get out of the human experiments--nature's experiments--are almost always confounded by various other factors than the one you are interested in. You've got to be very careful in trying to take into account the confounding, so that you might extrapolate to another population.

If I look at the results from an industrial population who have been exposed at high doses and I want to know what is going to happen in the community that lives down-wind--in the wind plume--from the stuff that might come out of the smokestack in that factory, I find that the people who are living down-wind are both younger and older than the mostly men working in the factory. They will probably have other illnesses. There are some of them who are sufficiently ill so that they are not working at all. Given this diversity I inspect that I really will have substantial difficulty even extrapolating from some humans to other humans.

The net result of this is that our difficulties, the risks in risk assessment, lie both in our lack of information and with the complexities of the world that may make the information impossible to get. I don't want to behave like the standard cookbook scientist who, when presented with a problem, says, "Get more data." You know, it used to be said, both jokingly and I think with some accuracy, that every scientific committee report had some boilerplate, which went into the report no matter what else was considered. The report went through everything that you did and then down at the end it said, "research needs." And the research needs said, "Get more data. These problems are not solved."

So what are the risks in risk analysis? The risks, as I see them, are one, at the moment, risk assessment is a mixture of art and science. By the way, I'm in favor of mixing art and science, especially in the Whithall Pavilion, where one must be in favor of mixing art as well as science in the presence of the Stradivarius instruments. Neither the art nor science in risk analysis is very good today. We're sort of in the cave painting era in terms of what we know.

That's art, but it's rather primitive--even more primitive than Grandma Moses. We are in danger of thinking that we know a great deal more than we do. We're in danger of mathematizing what we can do. When some people see mathematics, having been so frightened by it in elementary school they assume that the people who can do mathematics are somehow or other a breed apart, a different sort of person, and therefore you must pay attention to it and believe them. Since I was trained as a mathematician, let me assert, this is not true; don't believe us because we can do mathematics. We can do mathematics wrong just as well as anybody else can do their thing wrong.

I'm concerned with risk assessment. I think it's important. I think we've got to do the counting that was talked about earlier today. But I also think we've got to know that when we are doing it, we are on very shaky ground. We're doing very soft things. And there are enormous consequences that come from these soft things that we are doing. I am sometimes much more willing and much more anxious to trust the instincts of knowledgeable people--the people who have not done formal risk assessments, but have some sense through their life experience as to what risks are--than I am to trust my own computations.

So this is my concern, and I hope that in the discussion we'll be able to talk more about some of the specific things that were said, including some of the positive things. I don't want to be wholly negative. I was among the people who introduced the first techniques for doing some risk assessment and risk computations, and we were told that you can't do it, to which my reply was, "Well, we already have done it. How can you say we can't do it," and, of course, the answer was, "Well, you can't do it accurately," or "You can't do it correctly, or "You can't do it with precision," or "You can't do it to satisfy me."

The man who was talking was absolutely right. I certainly couldn't do it to satisfy him. I am afraid that I can't often do it to satisfy me. Thank you.

CIVIAK: Thank you very much. You've convinced me that small risks are difficult to estimate. One of the things that I think Richard Wilson was going to address was how we decide whether they're too small to matter or not. And maybe all the speakers are going to have to address that.

Are you going to give us 5 minutes on what you think Richard Wilson was going to address?

SCHNEIDERMAN (Impersonating Wilson): Yes, I will. I'm going to be Richard Wilson, you know. And I want you to know very quickly that there are some problems which are really not worth paying attention to. And problems that are essentially not worth paying attention to fall into several classes. Among them are the things that don't happen to you. If you don't live in New York City, you don't have to worry about being mugged . . . as much.

Excuse me, I forgot to say I'm a physicist, I'm not a medical doctor, I'm not a biologist. Physicists used to . . . have their training in computation and mathematics, and what I will present to you derives from my training as a physicist and in mathematics.

SCHNEIDERMAN (in his own voice): That's almost Wilson; it's not quite. I apologize, Dick, for this poor man's imitation.

I have a paper from Ed Crouch and Dick Wilson on some of these computational methods. They propose a computational method, and I'll try to tell you what it is. First of all, Wilson does say, let's consider an offspring or a child of the Mantel-Bryan "virtually safe" dose level idea--M and B say, one in a hundred million. Wilson says, let's consider one in a million rather than one in a hundred million. Annual one-in-a-million risk is roughly the order of smoking 1.4 cigarettes a day, spending one hour in a coal mine, flying a jet airplane across the United States--that's risk from cosmic radiation. That gives you an increased probability of death annually of about one in a million. (I think Mantel's one in 100,000,000 was a lifetime--rather than an annual risk.)

And Wilson says, "Really, look at these things, concern yourself with them. There are some risks that are so low that perhaps they are not worth public effort to reduce." They certainly may be worth private effort. They do affect you, and that's why I made that remark in the beginning about the risks that don't affect you are not worth paying attention to, where the ones that do affect you, you may be able to do something with.

Wilson proposes to look at carcinogens assuming the one hit model, (i.e., response linear against dose)--and then extrapolate from the animals to humans. His argument is this: in the animal systems there are a range of slopes of the dose response curves--that we get for different animal systems. Let's see what the distribution of the slopes is, and then let's take the upper 95 . . . or 98 percent confidence limit of this array of slopes among different annual species and assert (in effect) that man is probably no more sensitive than that 98 percent confidence limit slope. From that assumed slope for man, compute the risks to which man is exposed and see what this implies.

In this paper, Crouch and Wilson go through the computation that this implies. If you use the linear dose response you don't have to know what the distribution of exposure in the population. All you need to know is the average exposure in order to compute the risks for the whole population. Wilson computes the risk for the whole population, for various things--for saccharin, for the elution of acrilonitrile from plastic bottles, and a couple of other things.

Then he says, we'll look at the whole population. In particular, we'll look at heavy users of the particular material, because heavy users or heavily exposed people are at higher risk, and we'll see what the risks are for them. For the heavy users, he converts that risk to a lifetime probability of developing cancer.

I'll make an editorial comment at this point. I wish he had said, having done this computation, that this new risk is equivalent to the lifetime probability of developing, say, liver cancer, or that new risk is equivalent to the lifetime probability of developing cancer of the orbit of the eye, or that other new one is equivalent to the lifetime probability of developing acute lymphocytic leukemia. Data on these lifetime probabilities do exist. They were published by the National Cancer Institute following the third National Cancer Survey.

Wilson has not used them. I, for one have no good comparisons to make. If I look at a number that says, lifetime risk is 5.0 times 10 to the minus 2 for the 98th percentile of a person highly exposed to saccharin for developing blad-

der cancer, I don't know if 5.0 times 10 to the minus 2 lifetime risk is a high risk or a low risk. I need some measure to compare it against.

It's as if I was going to a foreign country and someone said to me, "Oh, yes, in that country you can buy a pair of shoes for 72 quasavawalus." Gee, 72 quasavawalus? Is that a lot or is that a little? I don't know what a quasavawala is worth in a currency I know--like dollars. And, literally, I need some comparison. And I wish he had given me that in this paper.

I hope, in view of Wilson's earlier attempts to help us understand what risks are by giving us that list of kinds of things we understand, such as smoking 1.3 cigarettes a week gives a one in a million increased lifetime risk and various other things--I wish he had done that with this paper too. I think it would have made the paper more useful.

If you want to talk about what he proposes in somewhat more detail, I do have the paper and we can talk about it later. Thank you.

CIVIAK: We could give everybody 5 minutes of what they thought Richard Wilson was going to say, but let's move one with what Sheldon Samuels thinks that Sheldon Samuels is going to say.

SHELDON SAMUELS: Thank you. I have some strong opinions about the methods that Sir Richard Wilson uses, but I will be fair. I'm not going to comment about him except to tell you that I looked forward to this meeting because the last panel I was on with him was in Kansas City before the Medical Writers Association some months ago, and he pelted me with little, tiny, pink packets of saccharin. I was going to retaliate by capturing and pelting him with some of my neighbor's cockroaches. I'm not saying this just to be snide. In fact, I want to talk about cockroaches because I think they lead us down a very merry path of risk assessment.

The Supreme Court recently decided, in an action that depends on social values little different from those that dictated the Dred Scott Decision, that the regulatory test accepted by public health practitioners literally for thousands of years did not apply in the workplace. I'm talking about the recent

benzene decision. When a sanitary inspector enters the kitchen of this library and sees one or more cockroaches, he's expected to order remedial action. The roach is associated with unnecessary filth, and filth is associated with disease.

He's not expected to count the roaches, quantify an association with filth, and relate a quantifiable dose of that filth with a quantified effect or a number of associated cases of diseased humans. That is not possible to do--least of all, because there is little direct evidence to associate cockroaches with disease.

For thousands of years we have prudently assumed that if we see them, the unnecessary filth with which they are associated should be cleaned up. The roach is thereby eradicated and the risk to health reduced. Now, the presence or absence of cockroaches is sufficient evidence. The pleas of management for quantification are considered meaningless as in an actual recent case in Alexandria, in which a restaurant owner complained that he should not have been closed down because there were only six insects on the wall when the inspection took place.

Now, while the courts were deaf to the restaurant owner, they were not deaf to the American Petroleum Institute. The Supreme Court did not discuss cockroaches, of course. What they did say was that before OSHA could regulate, they needed to establish a significant risk. And by that they meant an exercise in quantification, regardless of the scientific uncertainties, the uncertainties of process, or the double cultural standard that's required. The presence or absence of unnecessary filth in the workplace is not persuasive evidence. The operative values of the community--at least, legally--cannot operate in the workplace. The court confirmed the evidence of a case much like that described by Gunnar Myrdal in his study of racial discrimination, except that relegation to the case is not made on the basis of the color of one's skin, but on the basis of the color of one's collar.

A dialogue within the court on this issue has not concluded and so I'm still hopeful that a humane final discussion on the generating issue, which is the role of economics in health decisions, will come forth. But that dialogue occurs not only in the courts. It occurs in the administrative procedures of our executive

branch in a continual legislative reconsideration which all of you are involved in.

Those who lost, for example, in any of the various congressional struggles, lost the struggle for the congressional conscience in the beginning of this decade, now offer such analyses as risk benefit analysis as a last-ditch effort, labeling it scientific--ergo, good--and they directly or indirectly state that the earlier judgments were not a decision-making process at all or were not scientific--ergo, bad.

Now, the proponents are not all from those enterprises and interests who appear to bear the heaviest burden in congressional decisions. In fact, they come from academia, the Government, and the public health and the labor movements. I'm not just blanketly labeling my colleagues in management with a tar brush.

Because of the shortness of time, I'd like to concentrate just on one facet of the uncertainty factor,* which is not likely to be discussed: the cultural interpretation of scientific data. Let me relate this specifically to risk assessment.

Every science makes assumptions in advance of certainty. Systematized, these assumptions become a model, such as the kind of model which Marv has talked about, and they're used for predictive purposes or maybe sometimes to simply organize our data. The data is fed . . . some kind of fact matter, is fed into the model and conclusions are drawn. The conclusions are often compared with the product of other models. This can legitimately occur, but a common mistake is to argue about whether or not one set of conclusions drawn from one model is "true" compared to another set of conclusions drawn from another model. These assumptions or models and their products have heuristic meaning only. We use them only as long as they bear fruit--that is, we use them as

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* A copy of the paper from which much of this presentation is excerpted (recently published in the Annals of the New York Academy of Sciences) can be obtained by writing or calling the author.

long as they prove to be useful for the purpose of systematizing our data and for prediction. Only experience--by that I mean the ability of the conclusions that are pumped out of the model to withstand the test of time and further study--only that kind of experience makes them fruitful or not fruitful, heuristic or unheuristic. They are neither true nor false. Truth and falsity have little in common with models because they never can describe or represent all of the reality with which we're concerned.

Now, scientists generally understand and recognize this constraint when they're in dialogue with their own colleagues, but not all scientists are honest. The fact is that very often when they are in the business of vending their services, you have a problem, especially when the vending occurs among the congressional decision-makers. The vendors tend to not mention that constraint--that you're not talking about truth or falsity. Now, when they're challenged, they plead difficulties of communicating science or, privately, the stupidity of the audience.

We must accept some loss of meaning when we translate from one language to another, no less in the translation of scientific to lay language. But we can't accept total silence on the existence of the set of assumptions and their meaning that undergird the conclusions and judgments that come out of these risk assessment models.

I'm going to give you a specific example, and that is to be found in the controversy over the HEW report that a few years ago estimated the fraction of cancer attributable to occupation. Recently the Office of Technology Assessment commissioned Sir Richard Doll--another Richard--the Regis Professor of Medicine at Oxford and a frequent industry consultant, to critique that report.

Now, I realize perhaps I shouldn't have mentioned it because it was marked "Confidential, Do Not Quote," but I think Xerox passes those things out just to generate business.

Doll's rather emotion-dripping report--for the work of a scientist it really was loaded with emotion--arrives at conclusions different than those of HEW. In

effect, Doll said that the people at HEW were not telling the truth; that theirs was a gross overestimation of that fraction; that they made a lot of bad assumptions.

Now, I looked at the Doll paper in terms of what kind of model were they using, and I looked at the HEW paper. I'm one of those nonmathematicians who is not afraid of mathematics because I don't worry about the computations. I just worry about the assumptions That's a lot easier.

Sir Richard Doll wasn't talking about the problem from the perspective of working populations. All risk is relative, and to make a comparison of results he had to have a common perspective or broad denominator. Do you remember in the fourth grade how we were taught that things had to have a common denominator or you couldn't work with fractions? Well, people like Sir Richard Doll and Richard Wilson like to forget that.

There are no common denominators in their comparative analyses, which leads you to believe that maybe they're doing something a fourth grade student would not be permitted to do in arithmetic.

Doll was looking at the problem from the perspective of the general population. The HEW authors were looking at at the problem from the perspective of worker populations. There's nothing wrong with picking one view or the other. It's a question of understanding that then only assumptions can be compared. All assumptions, in a sense, are arbitrary. You select them, hopefully, out of some sense of experience, knowledge and judgment, but in an ultimate analysis logically and scientifically they're arbitrary.

Sir Richard Doll arbitrarily eliminated skin cancer from consideration. Why? Workers are exposed to ultraviolet on construction sites and in many other work places when they weld.

In the HEW paper they considered all sites with an excess of observed cases over expected cases. Doll restricted a critical part of his analysis of cancer incidence in the U.S. to dealths at age 64 or earlier. Sir Richard Doll's model uses a system, which is legitimate, of Newtonian single

cause, single effect. In the HEW document, they specifically say they want to get away from that and talk about multivariate factor analysis. In the Doll model, they use an arbitrary selection of agents (which was also done in the HEW study), but they use the International Agency for Research in Cancer list which, in fact, is longer than the list of known carcinogens that HEW uses. There are only six in the HEW paper.

Now, which is true and which is false, either in terms of the models or the conclusions? My belief is that neither is true and neither is false. The question really is, "Which are heuristic?" And, unfortunately, only future epidemiologic studies, as bad as they may be, can really tell us that. Meanwhile, to compare the models and conclusions, you must look at the kinds of internal decisions that are made and whether or not the use of the decisions follows logical rules. I'm not accusing Sir Richard Doll of not being logical. He was logical, indeed. But the decisions themselves are often mere unstated ideology.

There are other studies that could be compared, including a very honest report by my management colleagues in the food industry. The study of the Food Safety Council on a proposed system of food safety assessment starts out by saying that the procedure they offer us as a basis of risk estimation to man "transcends the boundaries of science in that it uses procedures of extrapolation which are consistent with known science, but extrapolation cannot be included in the vigorous boundaries of science."

I'm not really sure that that's correct, but that's what they state. I would think that extrapolation is no less scientific than any other predictive method. Anyway, they start off by being very conservative and very honest. And I appreciate that. They're up front, and that makes it a useful document in the grand dialogue that we have in Washington. They then examined four models for determining a virtually safe dose after stating that the VSD, virtually safe dose, "involves a judgment that is best left to the regulatory authorities." And they looked at the probit, logit, one-hit, various multihit models, etc.

They recommended none for all applications. None, they say, are "universally correct." In other words, they're essentially agreeing with the analysis of the reality of models that I'm suggesting. Now, how do they suggest that a model be selected for use in regulation? That is, after all, the key point.

They're very clear. They want to avoid methods of estimating risk at low doses such as one hit, in part, because that "approach will often unnecessarily preclude the use of substances which are of significant societal or industrial value." Elsewhere they say, these methods "can lead to undesirable and unsound results by distorting the balance between risk and benefit."

Now, let's just think about what the bottom line in this process really is. In other words, they're saying, that you pick the model--none of which are true and none of which are false--that rationalizes an existing economic value system. So they're working backwards. They're not trying to draw conclusions from science; they're telling science how to rationalize a preconceived notion. Now, this was a very valuable report because it marshalled a very high level of scientific thinking, it was very honestly expressed; and while we may disagree with the report, we can't disagree with that kind of openness.

The uncertainty in selection of the models derives from the uncertainty with which we as a society play with the value system, and that uncertainty cannot be resolved by science but by the legislature; and I certainly agree with my colleagues in the food industry on that.

Thank you very much.

CIVIAK: Well, now I don't know who to trust after listening to that.

SCHNEIDERMAN: Well, trust everybody but cut the deck.

CIVIAK: Okay. Now we're going to give our two discussants a little time to discuss. That will last about a half hour and then we'll open up to questions from the audience. Doug?

DR. DOUGLAS MACLEAN: First of all, I hope you all appreciate that it is a risky venture to discuss papers one has not seen in advance. Begging your indulgence, then, I will proceed. I think the discussion we have heard so far indicates

at least three different levels where controversies concerning risk assessment can arise. They can come up when we attempt to quantify risks in one way or another, when we compare different risks to each other, and when we attempt to determine which risks are bad, or not worth taking, and which risks are worse than others. The first, and to some extent the second of these levels, are aimed primarily at getting more and better information, information we need to have to design wise policies. The third--and to some extent the second--attempts to move beyond knowing to action. At this point, risk assessment moves beyond being a technique to better inform us, and becomes a practical or decisionmaking tool.

Dr. Schneiderman described some of the difficulties in doing tests and extrapolating useful data from experiments. He emphasized how little we know in even our best researched areas. So one of the informational problems of risk assessment seems to be to determine just how accurate our estimations of risks are. How good are our risk assessment tools, even at this level?

I am struck by Mr. Vaupel's comment about the relation of fear to actual risk. Vaupel suggests that fear--or public perception of risk--might be more in line with our best estimates if we take seriously the suggestion that people have a greater concern for low probability risks of catastrophic harms than for risks of more garden variety costs. Intuitively, this seems sensible; but there is a big question about the accuracy of our estimations, especially of catastrophes. Public perceptions <u>might</u> indicate a general belief that the probabilities of such events are higher than the experts think they are, not that the events are more greatly feared. We may simply lack very reliable methods for estimating the likelihood of events that occur rarely. This would be unfortunate for our attempts to reduce risks in a sensible and efficient manner.

Given a finite budget, there is only a limited amount that we can spend on controlling risks, and we certainly want to spend that money wisely. However, economic efficiency is not our only social goal. Neither the courts, nor especially the Congress, has its primary goal to make our society an economically

efficient one. Efficiency alone, furthermore, is rarely a sufficient justification for a public project or a law. It may serve to justify a decision where all the other goals are shared, and where the only thing we are debating is the best way to attain those goals. I am sure you know better than I how frequently or how rarely this is the situation when the Congress has to make some policy.

Now the techniques of risk assessment can also tell us something more than simply how to approach risk in an economically efficient way. This, I think is a most valuable lesson that Mr. Vaupel has so very nicely demonstrated here. Risk assessment can give us data and information pertaining to goals other than efficiency, and especially to the goals of equity or social justice. Only by getting quantitative data--by looking at and comparing different risks and how they break down across different social groups--can we understand which groups in society are more susceptible to environmental, workplace and other risks, than other groups. This should certainly be one of our chief concerns.

At this point, however, the adequacy of such techniques for decisionmaking becomes more problematic. This is the point, I think, that Mr. Samuels is making here today and also in his other writings. Equality and efficiency together are not our only interests. I take it that something like this is central to Mr. Samuels differences with Professor Wilson.

There are two problems. The first is the unreliability of the data. The second is that among our social values, in addition to efficiency and equality, we have to pay attention to some other less tangible, not so easily quantifiable aspects of our concern for human life. This is not to say that we cannot, in some circumstances, put a quantitative value on human life or on the amount we think it is appropriate to spend to protect human life. It is to say that the values of efficiency and equity alone cannot tell us when it is appropriate to quantify these things and what that value should be. As long as our policies pursue only the goal of trading off efficiency for equity, we are unlikely ever to reach a state where the public will accept the policies that are handed down. These are not, I believe, the public's only major concerns. Nor ought they to be.

Let me suggest just one thought experiment that might illustrate this point. This is the philosophical side of me coming out; I can't avoid it. Imagine that we became so efficient at transplanting organs that we could take a healthy person and transplant five or six of that person's organs in other people, saving five or six lives for the cost of killing one healthy person. Well, none of us would argue that we should introduce such a transplant scheme into society, where healthy persons would be taken off the streets and killed so that their organs could be distributed to save five or six lives. We would not permit such a scheme, even if the risks were distributed equally, and even if everyone's risk of early death were reduced in such a scheme, because the risk of dying now from organ failure is greater than the risk of dying would be either from organ failure or from being a victimized donor.

The scheme would be both efficient and equitable, but none of us would advocate a policy that would require imposing a risk that innocent, healthy people might be swept off the street and slapped on a table. The reason for this is, quite obviously, that acting in such ways, having such a social policy, fails to show a proper concern and respect for human life.

I think that issues such as this are at the heart of Mr. Samuels' concerns, and I think they are also alluded to by Dr. Schneiderman and Mr. Vaupel, too. Clearly, we need better techniques of quantified risk assessment than we now have, so we can know what our risks are and so we can compare them to each other. We want to know what we are doing, and we want to be able to target our risk reduction efforts effectively. But, at the same time, we ought to be very careful in relying entirely or too heavily on these methods--methods designed primarily to give us knowledge and usable information. We must be cautious in how we integrate such information into our decisionmaking processes, and we should guard against letting the data automatically determine our policies.

WARREN DONNELLY: It's been very interesting, listening to the discussion and the papers this morning. They certainly have held my attention, and they lead me to wonder about a few things.

First of all, there's a question of--assuming we really understood risk assessment and what it's limitations are--what could we do with it and why? I raise this question because we see throughout our society--and I think Professor Vaupel brought this up--the emergence of concerns about risks of all kinds. These concerns we find in organized groups. An Arms Control Association worries about the catastrophe of world-wide nuclear war. Various labor organizations are greatly concerned about the risks of exposure of their members to hazards in the work place, whether they be chemicals, or radiation, or whatever. Foreign policy organizations worry about other kinds of international tensions and catastrophe leading to war which, by definition, subjects a lot of people to all sorts of risks. The agriculturalists worry about the risks of a world-wide famine.

Looking at the technique of risk assessment, I wonder whether we might be led astray into a witchdoctor situation where we put a lot of credit on a very slender reed--which is a horribly mixed metaphor, but I think it will do. If there are lawyers present, I will apologize to them. What are we really trying to do? There's no easy answer to it. In Congress, which you all well know is a meeting place for every interest in the country and the clashes between them, all sorts of groups are pointing to these risks and to studies of them in support of their own particular position. We probably lack the benefit of being able to get the lowest common denominator that we have heard about this morning.

If we can get it, so much the better. But let us assume for a moment that we did really have a nice table of risks, every one with the lowest common denominator specified. We'd still face a political problem, then, of which risk is acceptable and which is not. If you rank them, logic would say you take the first one. But, there may be groups with all sorts of political influence which are much more interested in the fifth risk, or the twentieth risk, or the thirtieth risk.

I don't mean this to be discouraging, but I think the idea of using risk assessment, or relying unduly upon risk assessment, smacks a bit too much of

a technological utopia in which people are relieved of the burden of common sense thinking by relying on analyses that come out of computers.

A few specific things. The literature is obviously booming. I think that risk assessment is now the growth industry. A decade ago it was the environment, and a decade before that it was science policy. Here is a sample that I just got in the mail. It's from Rand which, is the Cadillac-class think-tank. I want to quote you from its summary. It says, a review of past regulatory decision-making leads to three basic findings. [This is about issues and problems inferring a level of acceptable risk.] They say, society has not been able to quantify acceptance criteria that are generally acceptable and applicable to all forms of risks. I think the panel this morning was a bit more optimistic than that but, none the less, there are differences of opinion. Second, different regulatory bodies as well as different members of the same regulatory body seek to attain different risk reduction goals, even for identical risks. Our own Nuclear Regulatory Commission is probably a good example. Here we have different commissioners holding to widely different assessments of risk for the same problem. Third, the acceptability of energy technologies varies significantly as a function of which risk reduction goals are used. This I translate to mean that if one is going to decide what energy technology to go for, one has to have in mind just what risk he is willing to accept.

In their conclusion--and here we come now to the perennial thought which was mentioned about scientific reports--they say: "Our conclusions and recommendations highlight some of the current conflicts among regulatory strategies and suggest the importance of defining these strategies in the form of explicit risk reduction goals in the design of safety research and development programs." Whenever I hear the words "research and development" it means putting off a decision until the next decade. As Rand sees it, first, the risk reduction strategy should determine the allocation of funds among R&D programs as well as influence the structure and aims of these programs themselves. Second, consistent strategies among regulatory agencies can promote efficient channeling

of R&D funds to the appropriate technologies and perhaps lead to a more consistent program of risk regulation and risk reduction.

Then they conclude, "How to best design such programs has been discussed only indirectly and needs to be the focus of future research which would include . . ." and then they go on for about a half page.

I have dumped some cold water on this discussion to moderate the great enthusiasm for risk assessment. Lots of other things have had enthusiasm, too. So I think if we approach risk assessment by realizing it is not the magic answer to all problems, we probably will be better off. End of comment.

CIVIAK: Well, Warren raised the question, if we really understood risk assessment, what would we do with it and why? Do any of the other speakers want to handle that? Sheldon?

SAMUELS: Well, I really agree with what Mr. Donnelly was trying to say, namely, that what you would do rationally is just forget about risk assessment in regulatory decision-making, because at this stage of development it is not even an art. It is not a science. It is not even an art, because it is a rationalization of an economic decision you want to make. We have to face up to that. Glossing it in science, as Marvin pointed out, is one way in which, hopefully, the bitter pill of social decision-making which is carried out here on the Hill is somehow coated to make it somehow easier for you to back down on decisions made in the last decade--whether you're talking about the Delaney Amendment or whether you're talking about OSHA or EPA or anything else.

You bring in these people with white coats and if they don't say what you want, you get another set of people with white coats and you keep going until you get the answers you want. Now, this does not mean that we should not quantify risk. And it does not mean that we shouldn't have a good sense of priorities and determine priorities based on real data. But this pseudo-science of risk assessment and risk/benefit analysis cannot take the place of sound political dialectic.

VAUPEL: Well, I don't think that risk assessment is a pseudo-science. I don't think it should take the place of politics, either, but I think that

some simple arithmetic, some counting, some comparing of effects can help improve the political dialogue. One of the main uses of analysis . . . I think a lot of people including analysts think of analysis as a substitute for politics, but analysis is not a substitute for politics; analysis feeds into politics. Analysis helps inform the political process. And one of the main uses of analysis is as follows. Suppose you have a disagreement--some people favor Option A, some people favor Option B. Then you do some analysis, you figure out, you find some new Option C that's better than A, and you find some new Option D that's better than B. Now you can fight it out between C and D, but you don't have to fight it out between A and B, which are inferior. Maybe you could do a little more analysis and find some Option E that everybody would agree would be better.

Now, I have managed to convince myself by studying this issue . . . I got into this issue because I was interested in knowing how we as a society could reduce the death rate as much as possible. I don't think the Federal Government today is doing a very good job of reducing the death rate. I think that the death rate is going down, as I showed you, but the efforts of the various regulatory agencies haven't been very effective. I want to reduce the death rate. I don't know how to do it through intuition, so I do some analysis. I do some analysis of what people are dying from, and what we can do something about, and that gives me some clues about how I can save some lives.

The notion that science is merely a rationalization strikes me as really missing the whole point of science--to try to find the truth, to try to find some information.

SAMUELS: Could I reply. I didn't say that science was a rationalization, and you're putting a value judgment on the use of the term "pseudo-science." Bertrand Russell, for example, pointed out that going through the stage of alchemy was an important stage in the development of real science, and that's what we're going through in risk assessment. At this stage I wouldn't call it alchemy, I'd call it necromancy, but at this stage that is essentially what we're going through. Now I'm part of that process we're going through and I'm

not ashamed of it. I'm not ashamed of the fact that I'm engaged in a pseudo-science.

VAUPEL: Now what you're doing is hurling epithets and hurling epithets, is exactly the opposite of science. I think you understand very well . . . Now I can hurl epithets too.

SAMUELS: Well, I guess Bertrand Russell was not a scientist.

SCHNEIDERMAN: I'll fall back on the demigod in my field, R.A. Fisher, who became a geneticist and statistician instead of becoming an astronomer because he was so nearsighted. He wore these very thick glasses and he really wanted to become an astronomer, but he said his sight was so poor that he couldn't find the telescope, and so he became a statistician instead. Fisher remarked that you are generally better off in the presence of data than you are in the absence of data. You are generally better off in the presence of information than you are in the absence of information. In this sense it seems to be important that we do the risk analysis type computations with the very serious caveat that what we are doing is tenuous, that it is chancy, that it depends on the models. Having done the arithmetic, having had it come out of a computer, it is important that we don't sort of stamp it kosher and say, "This is it. This is correct. This is the final thing."

Let's not do what the Club De Rome did--what came out of the Club De Rome report. Here was a computer analysis of where our society was going and hence somehow or other people invested it with enormous virtue. It was assumed that it was the correct analysis of where our society was going. Of course it strongly depended on the assumptions. I wanted to indicate some of the difficulties in risk analysis because I think that there is a tendency of some people, to place far more faith in the process than they should. But, as an adjunct to what we are doing, as a help to our thinking, as somewhat useful in policy development, I think it's important.

Now I want to give you an example of where I think risk analysis would go grossly wrong. Now those of you who are from tobacco-producing States listen

real harm, because I'm going to say something that appears to be nice, in contrast to what I said a couple of weeks ago in North Carolina--when I said that I thought that cigarette smoking was the single most important identified cause of chronic illness in the United States today. I still think that. Now let me do the arithmetic.

Cigarette smoking-related cancers constitute about 20 to 25 to 30 percent of all the deaths due to cancer. Let's say 25, that's an easy number. The estimated cost of cancer to this country including the cost of medical care, foregone wages and the various discounting things and all the other things economists put into these computatations was at least $20 billion last year. Maybe, what with inflation, it may be more, but that's a good round number. If I multiply 20 billion by 25% I get $5 billion as the cost of the cigarette-related cancers. Again, 25 percent of all cancers are cigarette related, the total cost is $20 billion; $5 billion per year is the cost to this country of the cigarette-related cancer. Now write down that number because I'm going to get back to it.

What's the value of the cigarette-related industry in this country? The value of the crop at the farm is about $3 billion; added value of the processing and retailing about $13 billion; added value of the taxes that are collected, probably another $4 or $5 billion; overall, including advertising cost the annual value of the cigarette based industry in this country is about $20 billion.

This is crude, but the number is roughly that. What is being proposed by the people who recommend that we save a lot of lives by reducing or eliminating cigarette smoking is that we substitute, essentially, for this $20 billion a year industry--wipe out a $20 billion industry--a $5 billion gain. That is the cost benefit ratio there, the ratio of cost to the benefit is roughly 4 to 1. Obviously we should not wipe out this industry, if we pay real attention to cost benefit computations.

I give you this example to show how I can get myself in trouble by not knowing enough. Here is a situation in which I've done what looks like reasonable cost benefit computation, which leads to what I think is a dumb answer. It's

a dumb answer from the point of view of the health people. Now it may not be a dumb answer from the point of view of the tobacco producers.

Are there things that I have left out? Well, I've left out a lot of information. I've left out other illnesses; I've left out some substitute use of the land now used to grow tobacco; I've left out some other ways that one can spend money on advertising, I've left out some other uses of tobacco.

When I was a kid living on a farm-we used a tobacco product as the insecticide. Black Leaf 40 was an insecticide. We used it to kill the lice on the chickens.

There are now people talking about tobacco as a protein source. I wanted to indicate that gross use or unthinking use or superficial use of some of the cost benefit or risk benefit or other risk computation analyses can get you in trouble. Nonetheless, I find myself in agreement with almost everything that's that's been said here today. I think we have to make these computations, but I think we have to be awfully damned careful and aware of what we are doing, and aware of our assumptions.

By the way, I'm not so hard on Sir Richard Doll as Sheldon Samuels is. I've known Sir Richard for a little over 20 years now. I was in the same department that he was in at the London School of Hygiene and Tropical Medicine. He and I have had some strong arguments about the estimates that we've made of the contribution of industrial exposure to cancer. We do come at them from different assumptions and we come to different numerical answers, because we've made different assumptions. But I think we can still talk to each other and that is still necessary.

VAUPEL: Can I make just one comment? It will be short. I would like to agree with Marvin Schneiderman's remarks about analysis. I don't want to be misinterpreted. I think analysis plays a very limited role, but that if you really want to save as many lives and limbs as possible, it is a critical role, although a very limited role. Usually when I look at a piece of analysis with my students, I'm horrified about how terrible it is. So I have to agree with Mr. Samuels, that most of the risk analysis that is done today is bad analysis.

Marvin Schneiderman's example is a piece of very bad cost benefit analysis that I think would be shot down by any good economist, but stuff like that floats around. Just because a lot of analysis is bad doesn't mean that there aren't some good people who know how to do a good piece of analysis. A good piece of analysis is usually pretty simple and it doesn't imply that good pieces of analyses can't play a major role with setting policy. I don't believe anybody could disagree.

SAMUELS: No I don't disagree with that, but let's think about where we're sitting. We're sitting in a place where before the Congress right now there is legislation specifying specific modes of analyses, which we as specialists in this field can't agree on. What is the meaning and how do you use the stuff? We can't really agree on what comes out. So the congressional question is, should politicians accept one-sided testimony as to what is appropriate and stick it into legislation or should they instead say there is not a quantitative judgment, but at the bitter end of all this there is a qualitative judgment that needs to be made? You need data to hone that qualitative judgment. You need data to balance information from my side, or from the industry's side, or any other side. That's all necessary. That's all, by the way, in existing law. But, I could not agree that you would take a specific mode of analysis, which at this stage of the game is pseudo-science--and I don't deride that, I've made that very specific--and stick it into a piece of legislation, and require that agencies jump through those hoops. Really, you would just make the beltway bandits very, very rich, because they're going to pump out identical garbage, just like the environmental impact statements are pumped out with boilerplate language. You would just keep the process going and keep the beltway bandits in business. We've got to stop that kind of Government.

CIVIAK: I think this discussion is going in a good direction. Let's keep it going for a little while longer. Did you have a comment, Warren?

DONNELLY: We've been hearing a lot now about the pros and cons of risk information. I didn't want to turn this into sort of a breast beating session

on limitations thereof. Rather, I'd like to put it into the positive sense, once again in the congressional setting. There are many members and staffs that are going to be faced with the outcome of risk assessments--It is the thing. Even if it does come from the beltway bandits, that just means it's thicker and heavier. There's a question then for you people who are going to be faced with this, what are the criteria, or the earmarks at least, of decent or good analysis? Is there anything that can be said to someone that's suddenly faced with a blast saying, our assessment shows this? What are some questions that could be asked so that you can probe and draw your own conclusion about how good is this particular piece of assessment?

SCHNEIDERMAN: Is that a question to the rest of us?

DONNELLY: Anyone that wants to field that one can enjoy it.

VAUPEL: I'll start. I think it should be intelligible, it should be written in English, it should use simple methods when simple methods will do. I would agree with Mr. Samuels that the assumptions should be very clearly stated, that when the scientist is making value judgments, the scientist ought to clearly demarcate those value judgments from scientific judgments. There shouldn't be an executive summary that leaves out some important information about underlying uncertainties. You know, you shouldn't give some point estimate, that becomes holy, in the executive summary without explaining how shaky that estimate might be. That's a few criteria.

SCHNEIDERMAN: I would add that it needs to be broad in the sense of considering, as well as possible, all the issues involved. At the moment for example, I am rather disturbed by some of the things that I see going on in risk assessments in relation to diet and various forms of disease. What has happened in my own field? We started out with a narrow scholarly study. Someone showing a correlation between breast cancer and fat consumption internationally. People said, "Ah ha, if you want to reduce cancer, want to reduce breast cancer, then we've got to reduce fat consumption." Then that went on and somebody else showed a similar correlation to fat consumption and cancer of the prostate and cancer of the colon, and that supported the argument. Those results remained in the

literature, until finally people looked at the relationship between fat consumption and all the cancers of the digestive tract, and by gosh there was no longer a positive correlation; it was now a slightly negative correlation. In other words, the first analysis looked at something that did have a relationship and made some sense, but did not consider the whole pattern of illness. We've now got, again in relation to the fat consumption and the risk assessments, we now have these very interesting and nasty and difficult conflicting reports that show increased heart disease with increased levels of serum cholesterol and decreased cancer of the colon with increasing serum cholesterol levels. What is the whole health effect? What is an optimal serum cholesterol level?

So now we're in the trade off position. Well if I were strictly a breast cancer man, and that was my only concern, I'd have not gone through any of the rest of the process. I think sometimes we're getting analyses that derive from a narrow point of view. So I would ask for greater breadth in looking at the analyses. I would also ask who did the analysis and I would ask if I could get some critical comments from persons who have looked at this analysis from another point of view. I don't find my fellow scientists venal. I know some of my fellow scientists do add to their income by being consultants to various people who have money, but I don't think they're being bought. I think these are people who have a point of view, and they will take a consultantship consistent with that point of view; not the other way around. I don't think points of view are being bought and sold. I think that's a nasty charge--and largely inappropriate. Nonetheless, I'm afraid that the risk and cost benefit analyses are almost always made from a fairly narrow point of view.

CIVIAK: I would like to open it up at this point to questions from the audience.

SAMUELS: I'd like to just add one other thing that should be added to considerations of risk assessments. One factor has not been talked about, and that is whether or not the risk is necessary. For example, benzidine: almost totally useless, almost totally substitutable chemical, used in great quantities throughout the world including this country; most of it is coming in from abroad, not

actually made here. Is a single case of bladder cancer, I'm not talking about death from bladder cancer, is a single case of bladder cancer worth all of the benzidine in the world? Is a single case of any kind of disease from any kind of food coloring worth all food coloring? Is the particular shade of a lady's Easter hat worth a single case of anything? Now I'm picking the easy ones. There are some tough ones, vinyl chloride for example, or lead. I could talk about important usesof arsenic. But, the easy ones nevertheless define the question, and I think that ought to be added to risk assessment.

MACLEAN: Along these same lines, because so many of the comments since the original presentations have concentrated on the difference between good analyses and bad analyses, I think another comment is worth making. It is certainly important to know what a good analysis is; that's one of the things that decision-makers have, unfortunately, to wade through risk assessments and determine. But there is a further question, and that is; even where we have what we all agree is a good analysis, what use are we going to make of it? Now, this, I think, ought to depend on many things. Consider the citation from Professor Wilson, that some risks are so low that they are not worth worrying about. Well, I don't know that the determination of any level of risk is, alone, enough to tell us that a risk is not worth worrying about. It depends on a lot more than that, including on how people feel about having different risks imposed on them. If risk is a potential cost, remember that fear is an actual cost. This is a fact we should attend to very carefully. To take just one example of an analysis, consider Jim Vaupel's wonderfully titled article, "Egg in Your Bier." Is this a piece of good analysis or not? Well, we can ask that question at different levels. Consider it purely as a piece of empirical analysis. The article is a study of cholesterol; what the dangers are; the connection to eggs; and the way people respond to news about cholesterol with regard to their egg-eating habits.

He takes most of his information about the dangers of cholesterol from other papers. I assume his information is right; I wouldn't know myself. But it is clearly laid out. At this level, the article is an excellent piece of risk assessment.

But how about as a guide to decisionmaking? Vaupel describes how giving up eggs altogether amounts to a minuscule reduction in cholesterol intake. Moreover, he points out that what we are likely to substitute for the eggs we give up might well result in a net loss rather than a gain in cholesterol reduction. This is useful information--information that we can make precise only by using analytical techniques. Why is this useful? Because, I think, people's concern about cholesterol is a common concern about one thing, so their interest in whether to eat eggs or not is the same interest. And this information addresses that concern. It shows that, given that our concern is about cholesterol and, perhaps, that is what it should be, the fear of eggs is misplaced. As a guide to rational decisions, this is excellent. But this is true not only because of the nature of Vaupel's particular analysis, but also because of the nature of the particular concern.

CIVIAK: Raising the topic of fear and public perception is another thing we can get into, maybe we will get into, but I would like to at least start and get one question from the audience.

DAVID TRAYNHAM: My name is David Traynham. I'm with the aviation staff of the House Public Works Committee. One thing we're dealing with, in terms of legislation that has been moving through the Congress this year, and probably will be next year also, is how to reduce the risk of flying. The risk is recognized as being very low right now as it is. Every time you got on a plane last year, it was about a one in a million chance that you would get killed in an aircraft accident. Nonetheless, the Government is now spending billions of dollars to keep that risk low and contemplates spending even more billions of dollars in the next decade to make it even lower. One of the things they are contemplating is drastically overhauling the air traffic control system to prevent the occurrence of midair collisions. The present system is regarded by a lot of people as antiquated and possibly leading to midair collisions. The thing is that when you look at statistics, and this is why I liked Dr. Vaupel's comments, was when you stop and look at the numbers, the risk of having a midair collision due to the air traffic control system, failing is unmeasurable,

because its has never happened. Yet,some people want to have the Government spend roughly $5 billion over the next 5 years to do something about this. What is the cause of the risk of being killed in an aircraft accident. Well its basically pilot error, or variations of pilot error, and very little is being done to do something about that. They are starting now to do something about it, but I think a lot of it has to do with the perception of the public, that you have this immense technological system and when something goes wrong with it--you have an aircraft accident--the response to it should be technological, when the problems are actually human. Somebody made a mistake, somebody was asleep at the switch or something. I think you have to look at the public perception. There is also a fascination with the type of disaster, the prospect of two fully loaded airliners colliding at 30,000 feet at 600 miles an hour is horrible, but it is also fascinating to lots of people. There is a lot of attention devoted to that. Having a pilot watching his altimeter as he is coming in for a landing is nothing particularly fascinating, but it is the thing that would improve aviation safety. I wanted Dr. Vaupel's comments about the perceptions of the public. How does the response of policymakers to technological problems tend to be technological rather than human, and then how does the fascination with disaster or catastrophe play a role in public policy?

VAUPEL: I want to answer your question first by being a professor, which means stepping back from the problem. I think airplanes are too safe, even though I fly planes a lot. What concerns me about spending $5 billion on airplane safety is that migrant workers don't fly airplanes. Poor people don't fly in airplanes. So it's a very elitist safety program. Spending $5 billion on rich people who already enjoy very, very safe conditions in airplanes strikes me as just morally wrong, given the fact that blacks and poor people and migrant workers have very high death rates. That's as a professor.

Then as someone who understands Washington a little bit, I would say, well, you're in FAA and you have your budget and you have to worry about what you

should do. I guess if I were in FAA, I would want to try to spend the money as efficiently as possible, to save as many lives as possible, given that that's where the money has been allocated. I'd try to make a strong pitch within the agency that if it's pilot error and you could save more lives through pilot training, then that's where you ought to spend the money. If it takes some effort to try to educate the public about that, you ought to try to do it.

TRAYNHAM: I don't work for the FAA, but I think that is their orientation.

VAUPEL: Congress, and you as an oversight committee, I think can play a role in making sure that the agencies try to spend their money efficiently and try to attack the real problem.

The whole issue of public perception is very important. I was really struck by Doug MacLean's remark that fear is an actual cost, and I think that is important. Obviously, our institutions have to respond to public concerns. Public concerns are a problem in and of themselves. At Three Mile Island, the fact that people were afraid of venting the radioactive gases made venting the radioactive gases expensive, in costs and risks, even though there wasn't very much actual risk involved. So, I agree that we have to be concerned about the public, concerned about public concerns but, if it's going to cost $5 billion to respond to some concern that isn't well based, then I would like to see Congress and the oversight committees, and so on, try to reallocate that money and reallocate the agencies attention towards the real problems we face and try to use the money wisely.

STAN DUNDON: I'd like a little bit more discussion on what we should do with risk analysis. My name is Stan Dundon and I work in Congressman George Brown's office and I'm a philosopher and historian of science. I work in ethics and public policy, too. I would say that a good Congressman, like my boss, and like all Congressmen who have the public interests and the solidity of our political system at heart, what they would want to avoid in this whole business of risk and Government's involvement in it is to avoid that total alienation from Government that occurs in the people when they perceive that

their lives, or other significant values, are threatened by Government or congressionally imposed serious threats to their health. There is another danger and that is one of loss of confidence in the regulatory process when there is a regulatory overreaction, such as, "oh saccharin is all right, you can use it now", but the next week it is not all right. That is a danger too, but I think a more serious one is that profound distrust that causes a kind of apathy or desire not to participate in the political process at all, or some kind of totally unconstructive opposition will occur, when you feel they're a bunch of asses that'll kill us if they have to, to get their political goals. Congressmen certainly, in their desire to get reelected, wouldn't want to see their people feeling that way. They recognize that we need that attitude of trust in our society and would like to see a lowering of risk, especially the risks that the Government participates in bringing upon the people.

Now in that context, I'd like to ask this kind of question, because there are bills up, like the Ritter bill and others. First of all, are we ready. . . I want to ask the panel what their personal opinion is, or anybody that's here--are we ready to legislate any kind of uniform and/or quantitative risk assessment system, not necessarily uniform, but any kind of system, any kind of rationalized system, and impose it upon the regulatory agencies at this time? OK, as opposed to perhaps just letting them keep studying the issue and finding the best technique they can use within their own agencies and so forth. That's one question.

The second question is, what good or need is there for additional funding or Government support of the development of the science and the philosophy of risk analysis at this point? Isn't this kind of dialogue that's going on, and the epithet hurling--which I'm going to say as a historian of science is important. Hurling of epiteths is very important; it generates passion. It gets people to go back to their laboratories and work and show that that jerk is wrong. There is really nothing wrong with it, but I think that we're at that stage now.

It worries me a lot that the Government might step in at this point and come down on one side or the other with a lot of money. So I'd like to know what people think about those two questions. Are we ready for legislation in this area in terms of imposing something on the regulatory agencies, and secondly, are we even ready for a lot of money, to be infused into risk-benefit analysis research?

SAMUELS: First, in terms of the adequacy of the funds--since that was your last question I remember that best. There are already sufficient funds for the most worthwhile projects, and funding is something which I monitor. Some of you know that I watch appropriations very closely in the field of health sciences. In fact, there are some projects being funded. that are really bad. So I don't think there is a question of the availability of money. One of the best studies for example, and it was done by the National Academy of Sciences, was a study on decisionmaking and risk benefit analysis, done at the same time that the Toxic Substances Act was going through. It was initiated by Norton Nelson, who then was chairman of the Board of Toxicology at NAS, and edited by Terry Davies who is now the executive vice president of the Conservation Foundation. If you look carefully at that study, even though the study is now 5 or 6 years old, you'll see the current state of the art in this field. It is an important field to pursue. I was serious when I said that the first stage is pseudoscience. There is nothing wrong with that, but at this stage of the game should the Ritter bill impose a pseudoscience on our regulatory agencies? My answer is no. Now, it would not be the first time that astrology has been legislated. To do so at this stage of the game, and I'm being very serious, would be doing an incredible disservice. You really would not affect the regulatory decisions. What you would simply do is slow them down and make them more expensive. Look at the bulk of the actual work currently in any of the regulatory agencies. You can write a standard in about 20 minutes, but it may take 20 years for the standard to pop out. Look at the

work that is going into it: phony cost/benefit analyses, phony risk/benefit analyses, phony environmental impact statements, phony economic impact statements. You can't make the system work better simply by creating more hurdles.

CIVIAK: I don't want to get into an extended debate about the Ritter bill, but does anyone else want to comment on whether we're ready to legislate consistency in risk analysis?

SCHNEIDERMAN: I think the Ritter bill, as I have been given to understand it, is overkill. I think it has some very useful and important purposes, but I don't think we're at the stage yet in which we want to legislate that much uniformity in thinking and procedures. I especially don't want to legislate uniformity (even inadvertently) while a science is developing. I think uniformity inhibits the growth and intellectual development that is absolutely essential before we learn how to do this well. I think the sections of the bill that ask for annual reports, and are you doing this appropriately, and that sort of thing are premature. I know Mr. Ritter and I've talked with him a little bit, and I approve of his goals, but I don't approve of the way he's going about it. That's why I think it's overkill at this time.

By the time that it won't be overkill, I think we'll probably not need it. Literally, because I think we'll be doing these things. I think what will come out of the scientific and intellectual ferment and the mixture of the lawyers and the scientists and the economists, will be good ways of doing these things. Once we develop the good ways of doing this, we'll adopt them, because they're the good ways of doing them, and we won't have to be legislated into adopting them. I like to think that the intellectual marketplace works--so that good ideas survive without coercion.

CIVIAK: I really do want to avoid getting into a debate about the Ritter bill, but I will recognize Barry Lubin, who works for Congressman Ritter, for a minute or two, but first Jim wants to say something.

VAUPEL: I just wanted to say that, before Barry speaks, that I've also followed the Ritter bill. I'm puzzled by this charge of consistency and uniformity. As I read the bill, it merely asks the agencies to do a little counting. I mean

counting to me is like motherhood. How can you be against counting what the health and safety benefits are of some action?

BARRY LUBIN: I'd like to say what the Ritter bill is and is not. It does not legislate any uniform approach to risk analysis. There are two bills. The first one was the comparative risk bill in which Mr. Ritter simply asked that the agencies consider comparative risk as a way of possibly getting some handle on how to evaluate an appropriate regulatory response. The second bill, which was just introduced, H.R. 8303, is a broader bill based on the first hearings that says comparative risk is really something that belongs under a whole listing, which we call risk analysis. There is an assessment portion, the counting that Dr. Vaupel has talked about, and a risk evaluation part--the political aspect of it--this is where the decision is made. Again, this bill just asks the agencies, here is a process, we would like a report to the Congress as to how this can best fit into your decision-making. I disagree with Dr. Schneiderman that evolution is the way to go about it. He possibly has more faith in the regulatory process than I do. I feel, and I believe Mr. Ritter feels that, if the agencies are to consider this type of approach, the Congress must ask them to knowledgeably consider it at this point, not 10 years down the pike. This is the point to interject Congressional interests into this process, not after it's gone helter skelter and it's too late to make any adjustments as to how agencies are doing.

CIVIAK: Do we have any other questions?

TOM ADAMS: Tom Adams, House Agriculture Committee. I work for Bill Wampler, who supports in a way, Mr. Ritter's bill. He has also introduced legislation for a National Science Council to solve some of these problems. I think the point is that some people, like Mr. Samuels, want us to solve the political problems first, when Mr. Wampler happens to think that you can't say there is anything at risk until you first establish that there is a risk. Then you go from there to discuss economics and politics. The problem in our committee, in the pesticide area and the food safety area, has been that the regulators are jumping on the bandwagon. We had a carcinogen a week last year. Beer was causing cancer,

nitrites . . . the point is we first have to establish what is a risk and if we can establish it, what degree is it a risk?

This is a scientific question, and I go back to the question that was raised last year, or several years ago, by the Office of Science and Technology Policy. I think it was also raised in the National Academy of Sciences' studies on saccharin. The same identical thing. Our feeling is, that before you can get to risk assessment, first you've got to establish if there is a risk. As the Office of Science and Technology Policy said, you have to come down with whether there is a high risk, a moderate risk, or low risk. Now maybe we can't do that, but we think that scientists who deal with the nature of deciding whether this particular cell shows cancer are probably better able to do this than anybody else. I don't think that it is a pseudoscience problem at all. I don't think that if you broke your leg you'd want to go talk to a witch doctor. You would probably end up with a doctor sometime. We think that you ought to go in this direction, and then start talking about what you do with benefits and all these other things. We've had the problem, constantly and all the legislators are having it every day, of somebody coming up from some regulatory agency and saying this particular product causes cancer or is a health hazard.

Now, I think Dr. Handler probably handled this thing as well as anybody else by saying, in a speech he made out at Northwestern University's new cancer lab, that we have a problem with oxygen. Now who wants to take on oxygen? Where do they want to place it? He says that in the Ames test oxygen shows as a rather high--and I would ask Dr. Schneiderman if he can confirm that--that oxygen shows up rather high in the Ames test as being a cancer causing substance.

SCHNEIDERMAN: Dr. Handler and I disagree on his Northwestern speech. There was a piece in Science that talked about our disagreement. I don't want to go into it any further than that, because I don't think it's germane to what we're talking about here. I've done some work on the problem of optimal dose levels for essential materials, and I think there are such things as optimum dose levels. I think those ideas have to get into the regulatory process. There are some materials that are essential at low doses and harmful at high doses, so there

must be some intermediate level which is least damaging, i.e., optimal. Oxygen obviously must be one of these materials. It's a little difficult to live without it, and yet at very high levels of exposure there are some serious dangers. Somewhere in between is best. The Greeks had a word (or two) for it: golden mean.

SAMUELS: I don't disagree with you about establishing that there's a risk, but that is not really the issue. Of course you have to establish that there is a risk. I wouldn't worry about the carcinogen of the week, because we only control the carcinogen of the decade. We control very, very few chemicals. I think you are probably right, that the newspapers sometimes do us a disservice by making a lot of fuss about something, but when it really comes down to it, we don't ban anything in this country, really; or in any other country, I might point out. I don't want to sound anti-U.S. The problem is what is the legislator, who has the prime risk assessment role, going to be telling the agencies to do. They are currently doing all of those things you want them to do. They are currently assessing risks and they are currently doing, whether I like them or not, cost-benefit analyses. For example, in an EPA report on radiation last year you had to read the footnotes in the back of a 300-page report to find out the critical piece of data, that they value the human life at a quarter of a million bucks and decided that only X dollars were going to be spent on a control of radiation from nuclear energy, and that's how they come up with their permissible exposure number. You had to find that in the back. As legislators, you want to be sure that they put that fact up front so it can be examined, and I'm all for that. But, I really question whether you need some generic legislation to do that. You need some good oversight to do that.

ADAMS: We are putting in oversight on these things, but the problem that we constantly run into is--let's take the saccharin issue or the nitrite issue--they started out in the regulatory agency, and while the Congressmen felt that they had accomplished something in assigning these issues to the regulatory agencies to handle, they ended up back in the laps of the Congress. Congress doesn't like that. So if they're going to pass legislation they are going to put it back out there somewhere else.

SAMUELS: I served on the NAS panel on saccharin and food policy. That's how I got into food policy. I'm not a specialist on food. It's just that two years on one of those panels gives you one hell of an education. I found out some very, very interesting things. For example--I don't know if this is really a discovery of facts so much as a perception--when you rank carcinogens, as the OTA report did and by implication the NAS report did (at least the majority opinion tried to do that) you can make some tragic mistakes. For example, it could be very misleading if you think of saccharin as a very low potency kind of carcinogen. The fact is--and this is a very good example of some of the pitfalls of what I consider to be a pseudoscience--that if you've got millions--to be accurate there are about 45 million people regularly exposed to saccharin, i.e., to a low potency carcinogen, that's one hell of a health hazard. You are right, there is a scientific issue as to whether or not it is a carcinogen. The agencies are dealing with that. I'm questioning this concept of potency.

I'm concerned with another factor also. In the NAS study we found out a very interesting fact--not a perception, a fact--the people really at risk are poor, black kids who spend 40 cents for breakfast by pushing a Tab button, even if they are skinny as a rail. Why? Because of social or peer group pressure. That's the best explanation we could come up with. So there was at least one group for whom--because of long latency periods involved with a kid beginning to do this as soon as he got his 40 cents for breakfast from his mother, when he began school or something--because of long latency periods, for that group, it was not a low potency carcinogen. The data, in fact, would indicate that for that group it was a high potency carcinogen. That's why these assessment systems worry me, not only as someone who is in dialogue with you folks on policy in my role in the labor movement, but as a scientist. I'm worried about that misuse of science.

ADAMS: We're worried about it, too.

CIVIAK: At this point I want to end the formal part. I think we can continue on with questions and answers for another 15 minutes or so, but if anyone feels the need to leave now, they can. I want to remind you that today we've talked a lot about risk and how we can discover what the risks are. Tomorrow we're going to have four people who are going to tell you what to do about the risks; how to manage the risks. We are going to continue here another 10 or 15 minutes.

SCHNEIDERMAN: Let me comment, since we're into saccharin. I remarked that Dick Wilson had done some computations on this. Remember I told you that his estimate was 5 x 10 to the minus 2 for a heavy user, 98th percentile; and I said that we ought to point out what that risk was comparable to. That was bladder cancer risk that he estimated from the animal studies. Five times 10 to the minus 2 is about the lifetime risk of lung cancer, in a white male in the United States today. Now that was one of his risk estimates. Let me say it again. For a heavy user--heavy user, defined as more than two cans a day--heavy user 98th percentile was about the risk of lung cancer in a white male in the United States today; the lifetime risk. Now that's a very high risk. It's a very high risk from this "low potency" material. So Samuels' remark about how we've got to look at the potency times the total population exposed, is of considerable consequence. I'll add another piece to it. It looks as if cancer rates for some exposures go up as about the order of the fourth power of the duration of exposure. Materials to which children are exposed then become of very much more consequence.

These are some of the things, I think, Jim wants to do in looking at the numbers; I think that this is what we've got to do. We've got to look at the numbers, we've got to make these estimates, we've got to do these computations.

I'd add one caveat about what he said. If we don't spend that $5 billion on aviation safety, I'll bet you anything you wish we will not spend it on the migrant workers. The money is not transferable. If you don't spend it on A, it does not mean you will spend it on B. You people know the legislative process so much better than I. The legislative process responds to people's

demands, and migrant workers are people of particular impotence in the political process and in part, I think, this is why we spend so little on them.

From the public health point of view, the most effective public health measures are the things that are done for you. We have this happen to us every day. The water that comes into my house is pretty good; in fact it's quite good. The sewer system that takes away the garbage and trash and wastes is quite good. Those plus garbage collection are the most important things in the community in which I live in protecting my health. That is all done for me so that I don't have to do it myself. The next most effective public health measure is something I have to do for myself once in a lifetime, i.e. get a tetanus shot, smallpox vaccination, something of that sort. That's the next most effective. The least most effective thing in the public health process is something that you have to do for yourself every day. Middle-aged men, like me, with high blood pressure, not like me, who are supposed to take their blood pressure pills every day, don't do it. They just don't. Yet high blood pressure is life threatening. They know it's life threatening to not take their pills, but something you have to do for yourself every day is usually not done. By the way, the interesting thing is that many women take the contraceptive pill every day. I think in part, because if you don't take them the consequences of not taking them are visibly visited upon you. If you don't take your blood pressure pills and you die, you don't know it. You don't have to live with the consquences the rest of your life.

SPEAKER: To what extent is the very process of doing risk benefit analysis or putting forward a system that is done through mechanisms that are to the lay person very sophisticated--the mathematics, the computers, and so forth--to what extent does that very process skew public opinion and put pressures on the system to bring about the expenditure of the $5 billion in aviation safety as opposed to migrant workers.

VAUPEL: You see, my hope is that if we do more analysis, we will be able to educate ourselves as to what the big risks are that we face. After educating

ourselves, we will do something about it. It seems to me that if more people knew how high the risks were to migrant workers, and to blacks, and to poor people, if we had some education about that, that might restore some social sense--you know some sense of social responsibility--in the United States, renew the concern for disadvantaged groups and maybe spur the political processes in a useful direction. As an analyst I hope that analysis can help us do better.

SPEAKER: Its not the analysis so much, as it is refocusing where the analysis is done. Just 24 hours ago, someone walked into my office with another problem because somebody did a study, somebody did some counting, somebody put the numbers on the table . . . and the report was issued. The report was full of assumptions which are not clear, and I haven't made a detailed study of it yet, but these have to be brought out. Of course the media has picked it up and there is now a political problem in that area, and a demand for a response that will trigger more attention there, not on migrant workers. That has come about because of a perceived need to put tremendous emphasis on doing some sophisticated analyses in areas where the tools are crude, the assumptions are many and varied, and of questionable reliability, but come up with multiple decimal point answers.

SAMUELS: I would agree that there is an extension of Calvin's dictum that if you don't measure it's not science, which is absolute nonsense, of course. This creates some public pressures. I agree with you. I'm for analysis and I'm for quantification, and we need more of it. We need more data. I agree with what Vaupel and Marv were saying, particularly Marv quoting Fisher saying that we're better off with data than without it. I agree with that. But, you see what's happening is that a specific mode of analysis is being advocated. Risk benefit analysis is not some general thing. It is a very specific thing, and I can give you a bibliography. It's a very crude thing, as Mr. Bogen, of the Congressional Research Service, notes in a beautiful paper he wrote recently. It's a benthamite thing, in which you have everything reduced to some kind of pleasure and pain calculus, even if it can't be. It's a very specific thing, and it's that specific analysis that many of us object

to. For example, I object--Marvin knows I love him, we're old friends, but in testimony and so on he says, we have to do risk-benefit analysis. If we really question him, and I have in OSHA hearings, and say, is this what you mean--no, no, he answers, I mean something else. You know what that is? That's a semi-logical fallacy, because you see what's happened is a switch in definitions, but only he knows about the new definition--no one else. So, even though he's an eminent mathematician, I always take umbradge when he uses those terms. What I'm suggesting is that--and Professor Lave has said the same thing, I won't be here tomorrow, but I hope he says this--we need analysis and we need examination.

I'm not worried about the press. You know it's OK if they kick us once in a while with a 2 x 4 and so forth. What I'm worried about is legislating something which at this point you can't legislate. We don't know how to do comparative risk analysis. If you look at Professor Wilson's tables, he's taking animal data and putting it in the same table with human data. He takes different kinds of animals, different kinds of humans, different kinds of human denominators, different kinds of animal denominators, puts them in one table and the table looks scientific

because it's got exponents in it. That kind of nonsense has got to stop.

SCHNEIDERMAN: Let me add a line to this. I think we haven't talked about something that is involved in stuff that I know Dick and some other people have worked on. We haven't talked about the difference between voluntary risk and nonvoluntary risk. We haven't talked about why people are much more concerned about risks that appear to be imposed upon them than ones they take themselves voluntarily. As Chauncey Starr showed, there are very serious differences there. The smoker is imposing a risk upon himself. Whereas, someone who is exposed to the water in his community in Nassau County, which has been polluted because a chromium plating plant up the road in Farmingdale has dumped the stuff on the ground and it has seeped into the groundwater, has no choice but to drink that water.

These are perceived as quite different risks and they are quite different risks. If I want to be stupid and take risks, I'll be stupid, but I don't want other people beating me on the head to make me take imposed risks.

SPEAKER: That's one of the reasons why I raised the questions I did. It seems to me at this point, and I'm not suggesting we slow down the quantitative part of this research at all, but the integration of the quantitative and these ethical considerations--the difference between consent and nonconsent, and so forth-- is way far behind. I'm not trying to find a job for myself as a philosopher, really. But, I don't think it takes a philosopher, you're quite capable, anyone's quite capable of recognizing that the probability of accidents in football for grade school and high school kids is one. You're going to get hurt sooner or later. Yet, who would compare that to the risk of a machine that the Federal Government requires you to have in your office that only kneecaps one out of a thousand workers. They're just not going to tolerate risks like that, even if it is only one out of a million workers who is kneecapped by that machine. That machine is put in there by Government law and if it doesn't have some justifiable purpose, no one is going to tolerate the risk. So we have to get some of that ethical work done.

I would say that one of the most startling things to me in the agricultural community, and that's the area that I'm most seriously concerned about, is when they talk about imposing risks that have no advantages to the public whatsoever and only have a marginal economic advantage to the agricultural community and if banned throughout the agricultural community would reduce them all to the same competitive position. However it might decrease their total gains across the industry. One example is the use of DES. I have never been able to figure out how they can compare that to DDT, which had a serious risk when it was introduced, but also a substantial benefit. But DES; what good are they talking about it?

SAMUELS: That's right. I'd like to mention DBCP also. That's another agricultural issue. In cross examining the extension service in the University of South Carolina, who were making a big case for the necessity of DBCP, I said,

what did you do before you had DBCP in peach orchards. They said, well we plowed the earth around the trees.

CIVIAK: I think this is a good time to end today's discussion. See you all tomorrow.

RISK: ASSESSMENT, ACCEPTABILITY, AND MANAGEMENT

Congressional Research Service Seminar

Whittall Pavilion

The Library of Congress

Thursday, October 23, 1980

MR. BOGEN: Good morning, ladies and gentlemen. We are now going to begin the second session of the Congressional Research Service seminar series on Risk Assessment, Acceptability, and Management, focusing today on alternatives for risk management.

My name is Ken Bogen, and I'll be moderating today's session. Congress has clearly been involved in the control of risks to health, safety, and the environment for a long time, but recently there has been a growing interest in possibilities for the coordination or systematization of Federal risk management activities. Dialogue and debate have developed regarding various proposed risk management schemes and their policy implications. These concerns have been reflected in recent legislative activity and heightened congressional interest in this area.

This CRS seminar series is an effort to bring together people and ideas in a forum designed to highlight issues of concern to Congress in its current investigation of the Federal risk management process and alternative strategies to improve this process.

Yesterday we focused on the methods and difficulties of risk estimation, comparative risk analysis, and risk acceptability decisionmaking. Today we shall focus on alternative strategies for managing risks, although there surely will be some overlap with yesterday's focus.

We are pleased to have with us today our four speakers: the Honorable Howard Markey, Chief Judge of the U.S. Court of Customs and Patent Appeals; Dr. Lester Lave, here to my right, visiting scholar in economics and public policy at the Brookings Institution; Michael S. Baram, professor of Law and Director of the Franklin Pierce Law Center's Government Regulation Program; and Dr. Fred Hoerger, Director of Regulatory and Legislative Affairs at the Dow Chemical Company. In addition, we shall benefit from the brief commentary and questions offered by our three discussants: Dr. Edward P. Radford, Director, Center for Environmental Epidemiology at the University of Pittsburgh's Graduate School of Public Health and former Chairman of the National Academy of Sciences Advisory

Committee on the Biological Effects of Ionizing Radiation (the BEIR Committee); Walter Hahn, a Senior Specialist in science, technology, and futures research here at the Congressional Research Service; and Dr. Vaughn Blankenship, a visiting LEGIS Fellow at CRS on loan to us from the National Science Foundation.

Our speakers' presentations will be followed by the remarks and directed questions of the discussants. Members of the audience will then be invited to ask questions of the speakers and discussants, and I will try to end the formal proceedings at around 12:00 o'clock so that members of the audience can introduce themselves to one another and/or continue with questions to the panel as interests dictate.

I remind the audience that we have coffee, tea, and cake on the table over there, so please feel free during the proceedings to quietly go over there and take on whatever health risks are contained in that selection. That goes for the speakers as well. I remind the speakers that these are not microphones connected to an amplifier. They're just taping devices, so try to speak up and feel free to stand when you present your presentations, comments or questions.

We shall begin with our first speaker, who has led three lives: as a soldier in two wars--he was one of our earliest jet test pilots, made Brigadier General at age 38 and retired as a Major General, Air Force Reserve with 16 medals and decorations. As a lawyer, he practiced in Chicago for 20 years, the last 12 as head of his firm. As a Judge, in addition to sitting in every case in his court, which sits always en banc, he is the first and only active Judge to have sat with every Circuit Court of Appeals in the land, having now sat in almost 1,000 cases and written over 150 opinions for these circuits in every type of case. Though he always credits the other four Judges, the fact is that the interval from filing to decision had been three years for many years when he came to this court. Soon the court was current and the interval from filing to decision has for years now been seven months. He is a member of the Judicial Conference of the United States, a member of the Board of Certification for Circuit Executives, Chairman of the Science Liaison Task Force of the Federal

Judicial Center, a faculty member at the Center, and Chairman of the Advisory Committee on Codes of Conduct of the Judicial Conference. He is a Fellow of the American Bar Association.

It is a pleasure to present the Chief Judge of the United States Court of Customs and Patent Appeals, the Honorable Howard T. Markey.

JUDGE MARKEY: Thank you, Ken. That was such a beautiful introduction it makes me anxious to hear what I have to say. Every speaker begins by talking about what a pleasure it is to be here. In my case, I think I may have at least one good reason for really meaning it when I say I'm glad to be here this morning. As Ken mentioned, I happen to have been one of the early group of jet plane test pilots in World War II, before any of you ladies were born, and as near as we can find out there are just two of that early group of seven who are still alive. So I'm glad to be anywhere, anywhere at all.

I hope in the next few minutes to stir up enough questions and so on and yet stay within the time requirements.

I hope to keep things in perspective. You heard what happened when the young lady wrote her mother and father from college, "Dear Mom and Dad, I am living with a boy without benefit of clergy. I am pregnant. I flunked math, and I'm being expelled. Love, Mary. P.S. I'm not living with a boy. I'm not pregnant, and I'm not being expelled, but I did flunk math. I just wanted you to have things in perspective." You can just hear the mother and father, "Isn't it wonderful She only flunked math Isn't that great?"

So I hope to keep things in perspective. Maybe one way to start is to realize that all life and all progress involves risk. There's no gain without pain. It has been said that when one gets out of bed in the morning he thereby subjects himself or herself to risk, then the statisticians run forth with a study showing that you can't stay in bed because most people die in bed. So it's a risk either way. Another wag has phrased the same thing a little more dramatically when he said, "Life is a terminal disease." But in today's world when the days of our lives are taken up with Government efforts to regulate

our risks, I put it to you that the management of the risks of living is and must be the business of the people, and that means the business of the Congress.

I've titled these remarks "Risk Management: A Congressional Chore." I'm not at all sure that Federal Judges immune from the political process should ever be involved, under any circumstances, as final arbiters of the degree of risk acceptable to the people. That task is much better performed by the people's representatives in the Congress, either directly or through delegation to an agency.

Unlike the courts, Congress and the agencies have investigative staffs and the opportunity for input from all segments of the public who are affected or likely to be affected by the approved degree of risk. I digress for a moment to mention how often it seems that when people speak of risk they really mean no risk. Paul Johnson has pointed to the two extremes, citing the rush into risk epitomized by General Custer on the one side, and the deadening, stultifying productivity- and progress-destroying effort to avoid all risk on the other, the latter epitomized by the hermited Howard Hughes in his effort to avoid all risk of contagious infection.

Indeed, to me at least, it seems clear that no society can exist riskless and free, nor would a life absolutely guaranteed and controlled against all risk be worth living. Such a life would lack all challenge, all accomplishment, all progress, and all fun. Though these considerations may be more sociological than legal, a drive toward either extreme must necessarily affect and be affected by the law.

In simpler times the law sought the maximum freedom of man to do whatever he wished so long as in doing so he did not hurt others. When man moved on and invented automobiles and split the atom and a few other things, the law moved on to prohibit doing what might hurt others. Thus, the law was forced to deal with the concept of risk involved in future or proposed conduct as well as with past conduct. Even so, the law to that point retained its negative nature in prohibiting injury to others. Many recent laws have now begun to enter an entirely

new thicket in this country, taking on a positive nature in prohibiting man from hurting himself. In that direction may lie George Orwell's vision of a society in which everything in life is either ordered or forbidden. All choice, and all freedom--for freedom is really freedom of choice--being thereby destroyed.

However that may be, the point on the total "risk--zero risk" spectrum at which the public has decided to live has serious implications for the law. Currently, on judicial review of an agency's decision, or an agency's risk assessment in which we're interested here, the courts will look to see whether the agency follows the correct procedures, whether it considered all the available evidence, whether it adquately articulated its reasons for its decision, and articulated a rational basis for its assessment. And that's it. The court will not, and in my view should not, substitute its own risk assessment for that of the agency.

In the benzene case, for example, the court did not decide that either one part per million or ten parts per million was an acceptable risk. What it said was that the agency's standard, one part per million, was not supported by substantial evidence and remanded the case to the agency to reconsider and see whether it could develop the evidence.

As hinted earlier, and contrary to some recent suggestions, I suggest this morning that there should be no laws which would bring the courts into the business of making the actual risk assessment itself.

I digress to mention that science, as we all know, is merely a synonym for search. That which is found is no longer science. It is technology. Congress has a role in deciding what searches to fund through what it wisely named its Office of Technology Assessment. I trust and hope that Congress will not ever, nor the courts, get in the business of assessing science--the search itself.

Throughout history there have been some who would prohibit particular searches, the most recent example being those who wanted to prohibit all research in recombinant DNA because "that is God's work." Researchers today must rely on the First Amendment's freedom to publish, and the derivative right to gather the data to

be published. I think and trust that if our Forefathers were writing the Constitution today they would include a clause reading, "Congress shall make no law abridging the freedom to learn."

Why do I say, "Let this cup pass," when it comes to requiring the courts to assess and analyze risks and benefits? There are many reasons. We don't have time for all of them. Maybe we'll hit some of them in the question period, but let's take just two. First, and it may sound strange in this power-oriented town for anyone to decline an offer of power, but the sociological, technological risk-benefit type cases, unless limited to questions of law, simply give us judges too much power. I speak, of course, only for myself. Other judges may disagree. It's been a long time since you've read, "This is a political, non-justiciable question," and the court declined to hear the case on that basis.

The cases of which I speak involve questions of broad public policy: the future direction of large segments of society; the level of acceptable risk; group preferment--the very things that legislatures were designed to decide. If our republican form of democracy means anything, it means that the people through their representatives shall make the basic decisions controlling their lives. The type and extent of the risk acceptable in their lives is, perhaps, the most basic of all those decisions. The power to make those decisions final should not be even indirectly vested in a few unelected bureaucrats who have virtual life tenure in their jobs or in a few unelected judges who have a constitutional life tenure.

The argument that the people and their representatives are incapable of making risk benefit decisions in my view simply won't wash. In the first place, that argument throws the American dream right out the window, the dream that man can govern himself. If we're ready to abandon that dream, the people should do it right out in the open. The dream should not die unannounced, unnoticed, and unmourned. In the second place, if the people and their representatives cannot now decide the level of acceptable risk, the solution for me is to design a decisionmaking mechanism that will enable them to do so.

So the first and primary reason for letting the "what risk is acceptable" cup pass the courts is that to let us decide is to preempt the people's right to govern themselves. The second reason, equally important, is that it can injure if not destroy the very heartbeat of a free society, the administration of justice.

The business of the Federal courts is to secure constitutional rights, to interpret Federal statutes, and to set forth the law in clear terms for the guidance of a society attempting to live free under the rule of law and not of men. In a word, the business of the courts is the administration of justice. The capability of the courts to conduct that business is impeded and may be destroyed when the people rush to the courts for broad public policy decisions like acceptable risk assessments; that is, when both legislative and judicial powers are handed to us robed beings on raised benches.

Unlike the beings who inhabited the cloud-draped heights of Olympus, Federal Judges are not gods. If courts assess risks, the administration of justice will be severely, if not fatally, wounded when the people find out a big secret. We can't do that job. The job requires, as I said, legislators responsive to the people and assisted by investigative staffs gathering factual and political input from all sides. It also requires recognition that there may not be an answer yet learned by science. Keep in mind, Judges majored in political science, English literature, philosophy, and so on. Many have never heard of the empiric method.

I think if you had the 900 Federal Judges in this room and asked them to write their definition of the empiric method, at least 80 would say, "What is that?" I don't mean to be smart-aleck. I want to make the point, but I don't want to overdo it. I can't speak for all the Judges, of course, but many have themselves written of felt inadequacies in fields of technology. It is perfectly natural. Many scientists would have difficulty fully understanding the dialectic method employed by the courts and the law.

The point is that many Judges have felt frustrated because they couldn't get an answer from the experts, not realizing that there may be no answer. When a body of experts recently was asked about the effect of fluorocarbons on the atmosphere, they said, "Well, we should appoint a committee and study it for

three or four years." Naturally. A perfectly proper answer. When a National Academy of Sciences panel couldn't agree on whether saccharin posed a high or a moderate risk, or on what they meant by high and moderate, how can you ask a Judge to decide? The courts are simply not equipped to administer justice and at the same time respond to the people's expectations when all the people's eggs, all their hopes and dreams, and all their risks are placed in the Federal judicial basket.

Whenever a Judge talks like this, some good-hearted folks think he's trying to slam the door of the courts against the people. Not true. He's trying to open the door that is not slammed, but is jammed by the crowds, many of whom need not be there and are keeping out those who must be there. There were 187,000 cases filed last year before 450 District Judges. Want to hear that again? 187,000 cases before 450 Judges. It's no longer a case of love thy neighbor. It's sue thy neighbor.

So don't make us the only game in town. Be chary of the power you give us. Too much will impede the exercise of our proper power to restrain the other Branches of Government from unconstitutional action. The trick, if freedom is to be preserved, is to keep the elements of Federal power in balance, to keep the three branches in balance. The trick, as our Forefathers so carefully intended in the Constitution, is to insure that no Branch, including the Judicial Branch, acquires excessive power.

But, you say to me, "What shall we do?" And a speaker should suggest solutions, not just problems. If the courts do not get into actual risk assessment, what should we do? First, the Congress should take another look at the 1946 Administrative Procedure Act, and the specific enforcement and review procedures tacked onto the 47 recent statutes creating rights to sue. Congress should provide, as it did for the International Trade Commission, that reviews should be limited to questions of law. That would have the benefit of keeping the courts working at what they know and do best, what they're trained and equipped to do. And it would have the benefit of maintaining the ascendancy of the only tamer of science we have, the law.

But, you say, if we're going to limit judicial review to questions of law, what will we do for folks who want to object to an agency's risk benefit analysis purely on technological grounds? They agree that there's no problem with the law, but they don't agree with the technological assessment itself, either in the scientific and technological criteria employed, the evidence looked at, the evaluation of the evidence, or whether enough . s looked at--all technological questions.

One answer may be to return to the people's representatives who created the agency in the first place and to do so through the congressional Office of Technology Assessment. I know Congress is swamped, but I am sure that there can be found among its 18,000 employees enough budgetary line items to enable the Office of Technology Assessment to establish a Review Division assisted by selected scientific advisers and consultants when necessary.

The Review Division would be limited to technological, not legal, considerations. It would assess any new evidence, the agency's scientific procedures, and the correctness of the agency's technological conclusions respecting the level of risk. That process, I hasten to add, would not, in my view, constitute even a type of legislative veto. If technological error were found, most cases would, I expect, be returned to the agency for further work. The Office of Technology Assessment would not control the funds or activities of the agency, but would merely assess the agency's technological conclusions, its risk assessment in a particular case. If impasse occurred, the OTA would report a focused inquiry to its parent, the Congress, where the final decision on the acceptability of that particular risk would be made by the people through their representatives.

I have not, of course, discussed this approach with anyone in the Congress or at the Office of Technology Assessment. It is a typical Washington ploy, a trial balloon. If it has any merit at all, someone may pick it up, and if not, wiser heads will prevail and it will, like these remarks, die aborning.

MR. BOGEN: Thank you very much, Judge Markey. Our next speaker is Dr. Lester Lave, from the Brookings Institution.

DR. LAVE: Equity and efficiency are often in conflict in economic policy. We economists give short shrift to equity while the lawyers consign efficiency to a secondary role. Formulating good policy requires attention to both.

There are two notable statements of equity and how to deal with equity issues. One statement came from Jack Kennedy in his inaugural address saying, "Ask not what your country can do for you. Ask what you can do for your country." A stirring notion. An earlier statement came 204 years ago from Adam Smith who said, in effect: "Forget about what you can do for your country. Just worry about what you can do for yourself." An important difference between those two is that when the free market governs equity, as with the Chrysler Corporation, then the consequence of inefficiency is bankruptcy or unemployment. Jack Kennedy asked people to put country before self-interest and promised that society sould take care of equity.

What we seem to be in the midst of right now in 1980 is a combination of Adam Smith and Jack Kennedy. That is, what we say is ask what the country can do for us while we're doing the best for ourselves.

Let me also say, taking the benzene case--if Judge Markey can talk about the benzene case, I guess I can talk about the benzene case--that my learned opinion from all my years in law school is that Justice Stevens was really trying to educate himself to some of the things you're going to hear about this morning. When Justice Stevens was talking about significant risk and about the extent to which an agency could impose standards, when the New Orleans Circuit Court was talking earlier about regulating, they were really trying in their minds' eye to match up what in the economic jargon is the statement that says that you should regulate risk down to the point where marginal benefit is equal to marginal cost. Of course, Justice Stevens never said it that way, not even the New Orleans Circuit Court said it that way. They did say that if you continue to draw down risk levels beyond the point where there is some roughly commensurate equality between the additional risk reduction that society gets and the cost society must bear, then society is harmed, not benefited. Society will stand for that

in particular cases, but as a general principle, society loses. And as soon as you start getting into that, then perhaps you don't get all the way to what Philistine economists do with their jargon and their mathematics, but you're at the basis of what is really the economic principle, namely, that we should worry a lot about efficiency. We should worry first about where we want to be, but having formulated our goals, we should get there efficiently. Furthermore, it one can't achieve some goals efficiently, then perhaps other goals which are less costly would be better.

I've been looking at a series of frameworks that can be used to govern regulation of social risk, and let me just sketch these out briefly.

There are seven frameworks I'd like to sketch for you. Almost all of these you've heard before. Almost all of these are written into congressional legislation of some sort. The first is market regulation. The higgledy-piggledy of the marketplace, all the individual consumers and all of the firms arrive at a safety equilibrium. The market is supplemented by the possibility that people can sue for redress if they suffer wrongfully. Congress in recent years generally has placed little confidence in market regulation of safety. However, the vast majority of risks that we face in our society are governed by this framework and and there is nothing that anybody is ever going to do to change that. There are just too many risk decisions to make Government regulation possible.

The second framework I want to talk about is no-risk, or the Delaney Clause [21 U.S.C. 348(c)(3)(A)]. The Delaney Clause says simply that you may not add a carcinogen to the food supply even if the calculated risk would be, say, one in a hundred trillion; if there is any risk at all, you may not add it to the food supply. Let me also note that FDA sometimes finds this rule a very hard one to live with. They have proposed that any risk of less than one cancer per million lifetimes will be considered to be zero. You may not have known that regulators can rewrite the laws of nature. Another way of putting the FDA rule is that, if you've calculated risk accuracy to five zeros, then you might as well just keep on writing zeros after that.

The third framework was proposed by FDA precisely because the Delaney Clause didn't allow it to make what seemed to be the sensible decision. It's called the risk-risk framework. It was proposed specifically for sodium nitrite where, on the one hand, sodium nitrite is metabolized into nitrosamines which are potent carcinogens. On the other hand, nitrite protects us from botulism, from the growth of Clostridium botulinum in the cured meat. A very, very rough calculation showed that you would probably expect more people to die of botulism if you banned sodium nitrite than you would expect to die of cancer due to the nitrite (or the nitrosamines). FDA, being worried basically about the consumers, said they didn't want to ban sodium nitrite because they felt that they would pose more risk to consumers or at least that the risk would be commensurate and nothing would be gained. The FDA didn't want to do what the no-risk framework called for them to do. They proposed going over to a risk-risk framework, but learned from the Attorney General that they could not do that under the current Food, Drug, and Cosmetic Act.

The fourth framework is one that the engineers have proposed. It's called risk-benefit analysis. At least to an economist, it sounds like the proposal of a set of engineers who didn't pay much attention to their undergraduate economics course. It says that you have to take all the risks and all the benefits and somehow balance the two. The large literature that's been accumulating in risk-benefit analysis, at least as I've looked at it, doesn't tell me what to do. It says you ought to balance one against the other without in any operational sense saying what should be considered, what shouldn't be considered, or how you should quantify risk, or how you should look at benefits--which is all a way, I think, of saying that you ought to be wise. The problem is that value conflicts abound. There isn't wisdom here. We need something more than just simply saying you ought to take all these things into account.

My fifth framework, which came primarily out of the Department of Defense, is called cost effectiveness analysis. It says that each agency should attempt to allocate its resources and attention in the most effective way.

If, for example, you're the FDA and your objective is to save consumers' lives, then you ought to be allocating your resources so as to save the most consumer lives. In particular, assume that by putting some amount of society's and the agency's resources into regulating sodium nitrite, you would saving ten lives per year. If you could put that amount of resources into, for example, regulating food contaminants and save several thousand lives per year, then this framework would have the FDA stay away from sodium nitrite and focus its attention on food contaminants where it could "get the most bang for the buck." This is an unobjectionable framework for almost anybody looking at the health area. It would say that Congress in its infinite wisdom should set the budget and goals of each of these agencies, then the agencies should try to achieve their congressionally defined goals to the extent possible within their resources.

The next [sixth] framework is an extension of the previous one. What's wrong with cost effective analysis is that the FDA does not bear the private sector costs of regulation. Cost effectiveness analysis is limited to the budget of the agency and its personnel time. If you ban or regulate a substance, for example, if the FDA succeeds in lowering aflatoxin tolerance levels from 20 parts per billion to 15 parts per billion, very little of those costs are borne by the FDA. They get imposed on the private sector. So what this next framework, the regulatory budget, does is to instruct the agency to take account of the costs that are imposed on the implementers as well as the agency. In order to do that this framework proposes that each agency ought to have two budgets. It ought to have an internal budget of the kind that every agency now has and it ought to have an implementation budget. That implementation budget would cover the costs to be imposed on the private sector or rather on all implementers. For example, the Congress might approve its billion dollar-a-year budget as the internal budget for the EPA and it might approve a $10 billion a year implementation budget for the EPA. With the first (internal) budget, the EPA would hire its staff, let out its contracts, and so on. With the second

(external) budget, EPA would make sure that it did not create regulations which imposed a total cost on all implementers exceeding $10 billion per year.

The [seventh] framework, the benefit-cost framework, is the one that we economists have been trying to peddle in Washington for more than 20 years and that has been used for water projects since the early 1930s. Here the framework is conceptually simple and, I maintain, conceptually nice. I don't know of anybody who can argue against it conceptually. In practice, there are a number of problems with it which I'll talk about, but conceptually you can't beat it. In implementing the framework, first you enumerate all the effects of some proposed regulation or other action. Second, you try to relate these and relate these quantitatively to the extent of the action. For example, if you're talking about air pollution abatement, then what would various levels of air pollution abatement cost? What would be the effect on ambient air quality? What would then be the effect on human health, on plants, animals, and so on?

At that point there's no objection to benefit-cost analysis, save the one that you can't do it. The next stop brings serious objections: you must translate this disparate set of effects into some common metric. What common metrics should you use? We economists are comfortable with dollars as a common metric, but, in fact, it doesn't make any difference which common metric you use. Not only do you have to talk about the cost of abatement in dollar terms, you also have to talk about the value of what you're going to get out of that in dollar terms. For example, to go right straight to the bottom line, you have to say what it's worth to society to prevent a premature death. And many Congressmen express horror at the idea that there is such a number.

Benefit-cost analysis falls afoul of two problems. The first problem is the difficulty of quantifying. I think that's the serious objection, the one that's worth talking about. The second objection is the difficulty of valuing things. That latter objection is not a very serious one because there are a host of ways one can finesse that. The first one is difficult.

Now, I will try to sketch out the application of these seven frameworks. Sodium nitrite, I sketched for you a second ago. It is a substance that protects

against the growth of Clostridium botulinum in cured meats. There's dispute as to whether nitrite itself is a carcinogen. Certainly, it's metabolized into a very potent carcinogen. Nitrite also has the property of coloring and flavoring meats. The question is what frameworks should be used, and let me sketch these very quickly.

If you use market regulation, then you wouldn't regulate nitrite at all, but simply try to inform consumers and let them make their own choice. For example, nitrite-free bacon is offered. If that's what you want, you can go out and buy it, or you can avoid all cured meats if that's your pleasure.

The no-risk framework is unequivocal. The no-risk framework says you've got to ban it; that is, that whether the nitrite itself is a carcinogen or whether it's metabolized into a carcinogen, it poses a carcinogenic risk which we can avoid. Ban it.

The risk-risk framework indicates that you don't ban it because you're going to lose more people from botulism than you would lose from cancer. Therefore, if what you're concerned about is the health of people, then you ought not to ban it. Now, the numbers here are very difficult. I don't mean to claim that we know with assurance that's true, but the best current estimates are that you would lose more people to botulism than you would to cancer.

Risk-benefit analysis, I don't know what means and so I'll just leave it alone.

Cost effectiveness analysis--if I were advising the FDA, according to this framework, I would advise them to not spend a minute of staff time on nitrite, because the number of people that are involved, that is, the total number of lives you're talking about, is something on the order of about a dozen. There are about a dozen lives each year that are at stake because of nitrite regulation. The FDA has bigger fish to fry than some regulation that's got all the trouble of nitrite associated with it and winds up one way or another affecting about a dozen people a year.

Regulatory budget--well, again, here I think that the costs on the private sector are huge. If you used a regulatory budget you would certainly not ban it.

Benefit-cost analysis--here you would begin to take into account the effect on consumers. Remember, if we ban nitrite, then everything that you now know of in the way of cured meats from corned beef, to pastrami, ham, and bacon, would all disappear; all these distinctive cured meats that many of us love would be gone. There is no current substitute for nitrite in terms of color and flavor. Those costs are large, and I don't think we want to ban nitrite.

Diethylstilbestrol (DES) is my second example. It is a synthetic hormone which was used--from the late 1940s through the early 1960s--as a drug for preventing spontaneous abortion in women. It was found after the fact to have been completely ineffective, but there were very large doses given to women which resulted in birth defects, primarily genital birth defects, primarily in the daughters of these women given DES, and also some cancers in the daughters of these women. DES has been used more recently as a growth stimulant for steers, for meat-producing animals. It reduces the need for grain and it reduces the time required in the feed lot by about 15 percent. The Office of Technology Assessment's estimate is that that might be anywhere from half a billion dollars a year to five billion dollars a year in additional costs with the banning of DES, costs to you as consumers. Even if DES is viewed to be a carcinogen and a teratogen and you use the standard conservative linear no-threshold extrapolations, you would estimate that by banning DES you would probably prevent one case of endometrial cancer about every five years and you would prevent, perhaps, on the order of about ten birth defects per year. These birth defects would presumably be microscopic ones with no real consequences. These estimates almost certainly overstate the risk.

If you use the market regulation, then you presumably do nothing about DES. If you use the no-risk framework which FDA has been using, then you ban it. That's the current state; FDA banned DES as of last November. The risk-risk framework is not applicable here and in general is not applicable. The risk-benefit framework, I'll wave aside. Cost effectiveness analysis--well, even if you believe that these extrapolations are correct, that you're talking about this very small number of birth defects and of cancers, the FDA again has

bigger fish to fry and should turn its attention elsewhere. So the cost effectiveness framework would say, "Look elsewhere." The benefit-cost framework would get you into the midst of a terrible dilemma, a value conflict. How much is society willing to pay in the way of increased beef prices in order to avoid, say, one endometrial cancer every five years and something on the order of a dozen microscopic teratogenic effects each year? I don't know the answer to that. I suspect that the answer is that society is willing to pay less than the half a billion to four billion dollars a year, but I don't offer that as a definitive conclusion.

Let me just go to saccharin for a second since it is one of these causes celebre. Under market regulation you simply put the warning on the package. You let everybody decide what they want to do. Under the no-risk framework well, FDA in 1977 banned saccharin. It concluded that saccharin was a carcinogen, even though a carcinogen of very low potency, and so it banned it. Clearly, the public did not desire that saccharin be banned because Congress immediately forbade the FDA from banning it. They had an 18-month moratorium on any action, but as of May 1979 that moratorium expired. FDA now has the power to re-ban saccharin. There is no evidence that's come to light which would show that saccharin is less of a carcinogen than they thought it was in 1977. So, legally, FDA is bound to ban saccharin. They haven't. I wonder why?

According to the risk-risk framework--unfortunately, nobody can quantify any health benefits that come from saccharin. There isn't really any evidence that people who use artificially sweetened beverages lose weight relative to having ones with sugar in them. If you're going to use a cost effectiveness analysis, again, the number of lives that are involved here seems to be somewhat small relative to other things that FDA can do, but I don't want to push that one too hard.

The real framework that I think is applicable to this is the benefit-cost framework, since people who use saccharin and are aware of the risks claim that even if saccharin doesn't really help them to lose weight that nonetheless it is important that they have this product. I am not a consumer of saccharin, but

I certainly have concluded for myself that I don't think saccharin ought to be banned.

Quick summary. Here are a set of frameworks that I have proposed. Congress has implemented five of the seven frameworks. It has not implemented the risk-risk framework or the regulatory budget. Given the framework that Congress desires in an area, and by Congress I am thinking of the elected representatives of the people, then it is relatively easy for an agency to regulate substances and to come to an agreement. The problem that we've had with social regulations so far is that the Congress has been terribly ambiguous about precisely what it wanted the agency to do. In the very few cases where it hasn't been ambiguous (as with the Delaney Clause), when the agency used it, the agency has lost its head. So, we've got to do something about straightening out what it is that society, as represented by the Congress, desires the agencies to do, and that's not an easy problem to solve.

MR. BOGEN: Thank you very much, Dr. Lave. Our next speaker, Michael Baram.

MR. BARAM: Well, thank you, Ken. I don't know who economists talk to or who they relate to, but this love affair with cost-benefit analysis is fascinating but troublesome. About three months ago, I was talking to a group of teachers who teach in a major school in the Boston area with friable asbestos ceilings, and who are very concerned that the school committee has not closed down the school. The Mayor has not authorized the appropriation of the millions of dollars that would be needed to take down the asbestos ceilings which are flaking. As we all know, asbestos in this form is the most proven of all carcinogens.

I was advising them on some of their options and told them about the Environmental Protection Agency's nonregulation thus far on asbestos, although the agency had started to develop algorithms and other elegant analytic approaches as to when it would and would not regulate facilities that had asbestos problems. These people at risk were not overly concerned about the elegant analytic methods. In fact, they had recently received a letter from the National Asbestosis Association, which had tested them, that 53 out of 180 teachers had symptoms of asbestosis. They were not concerned with the analytic methods, they wanted immediate action.

Thus, there are real human dimensions to these health, safety, and environmental problems with which the use of an economic framework like benefit-cost analysis can never really begin to cope. But I don't want to get into that subject today, although Lester has raised it and it really is a very tempting topic.

What I want to talk about today is risk management and its convergence with regulatory reform. Two critical problems are facing Congress today: [1] risk management, how to do it efficaciously and equitably; and [2] regulatory reform, how to begin diminishing the overburdening of the agencies, the overburdening of the public, and the overburdening of the private sector with more and more regulation.

Certainly, with risk management one talks about all these elegant, quantitative approaches and one assumes that there will be "superagencies" around to carry them out, agencies that will engage in more licensing, more and more rule-making. The Environmental Protection Agency (EPA) has just come out with probably 1,000 pages of regulations in one booklet for its Hazardous Waste Program under the Resource, Conservation and Recovery Act (RCRA), and it was required by Congress and the courts to come up with these regulations. EPA was years late, but finally came out with a monumental set of regulations, and sent out 30,000 copies to companies in New England alone. I've talked to people in some of those companies, and most are not even reading them. It's simply regulatory overload.

The regulatory overload is also felt in the agencies. The Occupational Safety and Health Administration (OSHA) has 2,000 fairly well-established toxins and carcinogens to deal with, as workplace hazards. It has taken ten years to come up with standards for about 12 or 14, and we know what troubles they've had, given the recent court decisions which have been discussed today. It's a very difficult process of dealing with thousands of chemicals in the workplace and there will be more and more each year as industry develops new products, which we want them to do to be productive.

So, where do we go with OSHA regulation? People have projected that it will be the year 2,400 or 2,500 or so before the presently known toxins and carcinogens are dealt with by OSHA regulation. Even a simple matter like a power lawnmower safety standard took the Consumer Product Safety Commission (CPSC) years to develop. What the reasons are is a complex matter, but one thing we know, risk regulation takes a long time and results in substantial burden.

EPA under the Toxic Substances Control Act (TSCA) has all the authority any agency could possibly want to deal with toxic chemicals. Yet, since 1976, when it received that authority, it has come out with exactly two regulations on existing chemicals: chlorofluorocarbons and PCBs [polychlorinated biphenyls], one of which was mandated by Congress in the Act. They accumulated a lot of data, and have done countless analyses and algorithms to reach these regulations. But there are at least several lists totalling several hundred proven carcinogens that still have to be dealt with, which the agency has just not moved on. It takes a long time. There are lots of uncertainties and challenges. Our administrative law system properly promotes accountability, and agencies properly try to come up with defensible regulations. There are economic pressures to stop too much regulation. So what we have is a system of regulatory overload on the agencies.

Now, to thrust sophisticated risk management methods and risk analysis options into this mess would be a serious mistake. I think we have to guarantee that the system we use for risk management will be responsive to human needs and to new health and safety problems as they are identified, without the burdens or the delays, or the self-serving involvement of a lot of the risk analysts, in this process.

Now let me get to what I think is a solution to both of these complicated problems, risk management and regulatory reform. It's a very simple solution, namely, to develop a new role for the regulators, the role of relying on <u>alternatives to regulation</u>. That is, the regulator, vested as he is with authority to deal with health and safety problems, should retain that authority under the

statutes, but only use it in a rule-making fashion as the ultimate way of dealing with risks. Prior to any rule-making, the regulator should use whatever discretion he has to try to develop and activate non-regulatory options for dealing with these risks.

Some of these non-regulatory options are well known to you: industrial voluntary standards, doctrines in tort law like nuisance and negligence, private insurance schemes, government procurement power and the influence of Government in general through education and information, as well as a variety of other options. It seems to me that it makes more sense for regulators at OSHA, for example, to sit down and strategically plan on how workers' compensation law could be modified to be more effective, and how negligence doctrines might be better employed by workers, with technical advice and assistance from OSHA on some of the causal connections and difficult evidentiary issues. Thus, a modification of workers' compensation laws might be reached so that they would adequately compensate for chronic occupational health hazards caused by carcinogenic chemicals and other new kinds of exotic health hazards in the workplace. This would generate feedback to industry on future costs and insurance rates, and industry could then take preventative action so it would not incur such high costs in the future.

Therefore, it seems that agencies such as EPA and OSHA might be best advised not to try to regulate each of 2,000 chemicals at the pace of six years per regulation and at the expenditure of a large sums for a lot of risk analyses. Instead, they should foster and develop a <u>generic process</u> that would be effective for dealing with these problems--a process which puts responsibility on the private sector, a process which in the case of OSHA would involve reforming workers' compensation law, providing technical assistance and even financial assistance for unions or workers who express the need for technical help in using doctrines of tort law, like negligence and product liability law, or for working towards better collective bargaining outcomes.

Similar considerations apply to other areas of regulation, for example, the regulation of safe automotive design by the National Highway Traffic Safety Administration. Consider the problems in regulating Ford Pintos, the endless stream of regulations dealing with automotive safety and design, regulation of welds, of bumpers, of glass, of automobile frames and many other things. Can we ever really regulate safety in consumer products like the automobile, which are subject to various types of uses? It might be advisable for an agency like NHTSA to begin thinking through what doctrines of product liability law under the new Model Product Liability Act, might be of use here, as well as what industrial voluntary standards could be established. Finally, NHTSA might look at insurance rate structures to see to what extent these could, through better rate specificity, focus on the high risk automobiles and users and provide higher insurance rates for those who want to drive the Pinto or other cars that may be more dangerous than other automobiles. Thus, a selective, strategic approach to deal with the future, with its endless stream of problems that will come before the agency, seems to be called for.

Now, none of this is new. It might be said that the common law hasn't worked in the past, and all these alternatives being suggested haven't worked: that in fact, that's why we have regulations today because none of them worked. Well, I think with a little agency muscle and strategic planning, to identify and foster these options, the agencies could begin to create a process approach for dealing with innumerable problems on a cost-effective and equitable basis.

In a study for the Ford Foundation, my associates and I have tried to develop this new role for the regulator, to spell out what some of the options are outside the regulatory system for managing risks; to spell out procedurally what the regulator can do, using his discretion, to begin to foster the use of such options, while retaining the ultimate authority to regulate by rulemaking if the options don't work.

We have also spelled out what some of the legal obstacles will be. Obviously, many will start suing a regulator who doesn't regulate, a regulator who wants to

go out and get industries and other affected interests together on a particular risk to work out a system for dealing with that problem in a manner which obviates the need for coming up with difficult rules on an ongoing basis. This report begins to open up a topic that I think might be a very useful way of resolving both the risk management and the regulatory reform problems that seem to be besetting us. 1/ Further work on this subject is now being done under grant from the National Science Foundation.

Certainly, a number of other problems may arise, for example, if OSHA seeks to reform workers' compensation law. There is no guarantee that each of the 50 states will adopt these reforms, but there are vehicles that the Federal agencies can use vis-a-vis the states to ensure that states begin to put their systems in better working condition. OSHA, EPA, and other health and safety agencies often enjoy a certain kind of relationship with states in which Federal authority can be delegated to the states provided the states act consistent with what OSHA or EPA require under a particular statute. Thus far, this has been construed by Federal agencies as requiring state "incorporation by reference" of all their regulations. But there's no reason why a state could not come up with its own particular scheme using workers' compensation, product liability law, ombudsmen, and other devices to manage risks perhaps as effectively or even more effectively than a Federal standard-setting approach. There will be other problems with this approach, but each is workable and we are continuing our study to help this reform established.

Certainly, the task for each agency of using alternatives could be simply stated by Congress, by means of a generic amendment to the Administrative Procedure Act; or it could be done by the President's Office by Executive Order, or by each agency unilaterally, to the extent permitted by enabling laws. This task would

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1/ Baram, Michael S., et al. Alternatives to Regulation for Managing Risks to Health, Safety, and Environment; Report to the Ford Foundation. Concord, NH, Franklin Pierce Law Center, 1980. 219 p. In a subsequent second report, case studies addressing the use of alternatives for three problems, are presented-auto design, high-voltage transmission, and hazardous waste management. 1980. Both reports will be published by Lexington Books as a single volume in August 1981.

consist of a duty for each agency to identify the risks that fall within its jurisdiction, to prioritize those risks in some rough fashion, and to then develop options for dealing with those risks by means other than rulemaking where feasible. Certainly, for nuclear power or certain other fields, the options may not be adequate or acceptable. For consumer products risks, workplace hazards, or the many environmental hazards, however, the options may very well be there. After identifying the options, the agencies should try to identify what their limitations might be, develop recommendations on what has to be done to put those options into better working condition to deal with the risks, and then try to foster the adoption and use of the options. This may mean returning to Congress for legislative action to ensure that the options are available in proper form.

If none of the above works, regulate. But I think it's time for us to rethink the whole regulatory process. Clearly, the thousand pages of EPA hazardous waste rules will be followed by another thousand pages--interim amendments have already been proposed under the one RCRA program. Some small companies in the private sector are now beset by rules under some 20 regulatory programs affecting chemicals, biologicals, and other hazardous products, often with overlapping reporting requirements and other attributes that few people can understand or comply with.

Thus it's time to rethink where we're going with health and safety regulation. I'm not here to dismantle or to suggest dismantling the regulatory process. What I'm suggesting is a fine tuning of the role of the regulator, to urge more use of strategic and more cost-effective options. Thank you.

MR. BOGEN: Thank you very much, Mr. Baram. Finally, Dr. Hoerger.

DR. HOERGER: My industrial background includes considerable experience in activities associated with risk management decisions. This experience includes the design of programs to generate new data on risks, assessment of the risks associated with a variety of chemicals, design of practices and policies for controlling or managing risks, and participation from the industrial side in numerous regulatory arenas. This experience leads me to the conclusion that the most

difficult portion of risk management decisions involves more than the assessment of the risks associated with a chemical or activity. It includes the assessment of risk reduction possibilities via various alternative control mechanisms.

The typical questions from our manufacturing and operating personnel illustrate this point. The sophisticated plant design engineer asks the health professional for the emission level to which we must control. He wants a specific number. The plant manager's intuitive question is, will this work practice control the hazard? Many of the questions from the plant worker, who is informed that a chemial such as formaldehyde induces cancer in animals, focus on the significance of the finding in terms of his personal risk. Similarly, the Supreme Court decision on benzene focused on the need to address the significance of risk. Congress, in asking the National Academy of Sciences to address the saccharin issue, also asked for a judgment on risk in a sense to put the risks into perspective with other risks.

It is my premise today that we can and should upgrade the quality and precision of our risk estimates. We thereby set the stage for better regulatory policies and for better implementation of regulatory alternatives. In developing this premise, I wish to point out several deficiencies in our present regulatory approaches to risk management and then make several recommendations for congressional study or adotion.

A major deficiency in present public policy is the almost exclusive focus on government as the sole mechanism for managing risks. We minimize the many significant activities of industry in both assessing risks and in managing risks. Let me sight a few facts and practices about my company, the Dow Chemical Company, as typical of many corporations in America today. Dow has an extensive health and environmental organization consisting of some 225 people who are involved in all aspects of toxicology, industrial hygiene, environmental science, and medical activities relating to the generation of data needed to identify and quantify risks. Additionally, there is a comparable number of people applying this information to our manufacturing operations and making recommendations for the transportation and use of our products.

Another example of an industry initiative is "Product Stewardship". In 1972, Dow adopted a strong corporate policy statement formalizing the concept of product stewardship, basically an active program concerned with the identification of problems, both current and anticipated associated with the manufacture, distribution, use and ultimate environmental fate of our products. This corporate policy permeates all segments of the organization.

Additionally, the industry, through collective efforts such as the Chemical Industry Institute of Toxicology special testing programs, in stewardship of academic research is doing much to identify the risk potentials of their products. A few companies have even established organizational units dealing with risk management practices on a broad public policy basis.

Another sector that contributes much to the risk management practices of the country is academia. The training function is of course well understood and appreciated. Additionally, academic institutions are on the leading edge of research associated with health effects. To a large extent these academic experts are used by the Government on an ad hoc consulting basis or are involved in somewhat menial fact collection tasks. We do not today have a strong thrust toward gaining the continuing best expertise of the academic community in public policy considerations on risks.

In my view a second deficiency of current public policy is that the generally accepted report card of the regulatory agencies is the number of regulations issued per year and the stringency of these regulations. This report card forces the agency into an early advocacy position on a given issue and blunts their motivation for extensive fact collection and identification of research needs.

The third public policy deficiency that I would like to emphasize is our lack of perspective on risks. This lack of perspective can be expressed both as a lack of relative risk bench marks and the inability to separate speculative risks from known risks. This lack of relative risk perspective places considerable doubt on the wisdom of our priorities and the need for marshalling extensive

resources for risk reduction programs. These deficiencies in our present public policies lead me to several recommendations.

My recommendations all relate to upgrading the quality of science and fact available to the decision maker. It is my premise that Congress can bring expert science to bear on the assessment and quantification of risks, make scientific peer review an essential component to both the fact collection and the assessment processes, and that the regulatory decision process can readily accommodate this increased emphasis. Finally, I believe that Congress should commission a number of studies to improve our bench marks of risk. If these changes are made then I believe that perceptions of risk and needed risk management practices will be clearer and more readily accepted by all sectors. The result would be greater harmonization of industry risk management practices, with generally perceived needs and a lessening of the amount of regulation without lessening the control of hazards.

My first recommendation is for the establishment of a science panel to make risk assessment determinations. This concept has been developed by the American Industrial Health Council and has been discussed with a number of members of the public policy and scientific community including some congressional staffers. The concept is relatively simple. We should bring the best scientists to bear on determinations of carcinogenicity and other chronic health risks. Conceptually, the panel might be composed of 15 to 25 eminent scientists nominated by professional societies and selected by a group such as the National Academy of Sciences. This panel would be supported by a small staff and would have the responsibility for the determinations of whether or not materials are carcinogens or whether they pose other chronic health risks. The panel would also address the question of the quantification of the risk in the most reasonable manner available to science. Let me hasten to say that this determination and quantification of risk would be both a fact and judgmental input to the regulatory process. The regulatory process would then have to make the societal decision on the acceptability of risk and the degree of control necessary to achieve that

societal goal. We clearly endorse the fact that the societal decision is a regulatory decision.

My second recommendation is for greater use of scientific peer review of regulatory homework and proposals and for incorporation of this peer review at an ealier stage in the regulatory process. During the past year there has been considerable focus within the agencies, in the media and in the Congress on the need for peer review. Congress has established the precedent by authorizing numerous science advisory boards which largely perform a peer review function. Operationally, I believe there are two flaws in the present approaches to peer review. First there is no uniform encouragement of such a practice. Second, and perhaps most importantly, the existing peer review processes focus largely on regulatory proposals. In my view this is too late. The focus is after the agency position is pretty well frozen. The agency scientists are put into a defensive position rather than remaining in an open position for constructive comment. Additionally, much of the agency fact collection is a mish-mash of short-term assignment necessitated by enforcement policy or the need to issue a white paper on a predetermined agency course of action. Consequently, the science advisory boards are often asked to comment on poor quality work. It is not very productive or helpful to the regulator to have eminent comment on a garbage heap of work product. It is my belief that the peer review process should be targeted at the fact collection stage of agency activity.

My third recommendation relates to integration of the science panel and peer review process. (See the summary appearing on the following page.) I present it as a strawman and recognize its simplicity and need for considerable development.

One can characterize the present regulatory approach along the lines of, first, the recognition of a perceived risk and then agency evaluation followed by either the assignment of a priority for regulation or a rejection as not needing regulation. If the agency decision is to proceed with regulation we then embark upon a lengthy regulatory political process that includes agency fact finding, an advance notice of proposed rule making, a regulatory proposal, public comment,

public hearings, perhaps an agency reproposal, a final regulation and then, frequently, lengthy court proceedings. Where the risk is not well defined, where the agency proposes a stringent regulation inconsistent with control of similar risks, or where costly economic consequences are attached, this process usually consumes several years. This sequence can be illustrated by the saccharin, nitrite, DDT, or the vinyl choloride air emmission controversies.

It is my proposal that we could bring the science panel in for peer review after the initial agency assignment of priorities. Upon the request of the regulatory agency, the science panel would make a preliminary determination and their best judgment on the degree of risk based upon the available data. Additionally, the panel might make recommendations for fact collection and research.

The agency then would develop plans for fact collection and research, adding their experience to the recommendations of the science panel. The fact collection and research proposals would then be referred to the science panel for peer review. The modified agency program would then be implemented by government, academia and industry according to the circumstances and division of the work. Upon completion of the fact finding and the research, the science panel would examine the data and make a final determination of risk. They would express as quantitatively as possible the degree of risk and the uncertainties on their risk estimate. This recommendation then would be the basis for agency consideration of whether or not to regulate and the various regulatory alternatives.

This integration of the science panel and peer review would in my view do much to improve the quality of the fact base available to the regulatory agency and by bringing eminent judgment at the early stage should significantly minimize the degree of controversy associated with the regulatory actions that would follow.

My next recommendation relates to obtaining better perspectives on risks. I believe that Congress should do everything possible to encourage new studies on relative risk. Personally, I believe it is possible to develop relative risk bench marks. We already have statistical information relating to automobile accidents, various types of consumer injury, various recreational incidents and

many occupational hazards. This statistical information can be arranged along a spectrum from a relative risk of one in fifty of dying in an automobile accident during a person's lifetime to one in a million for a number of the chronic health risks associated with chemicals. I recognize that my statements here are overly simplistic; however, I believe that it should be possible to commission studies which would develop highly beneficial spectrums of risks in which commonplace risks were displayed. New risks under consideration could then be plotted along this risk spectrum for perspective. Degrees of uncertainty could be outlined on the spectrum. I do not propose this as an absolute or binding formula for decision making, but as a judgmental consideration for both the decision maker and the concerned public.

Along with the studies which would provide greater perspective on relative risk, additionally, I recommend that Congress commission studies to estimate the risk reduction possibilities of numerous national programs concerned with safety, health, and environment. Our present national efforts represent significant outlays of both human resources and dollars. For example, I would estimate that the Federal and private outlays for reduction of cancer risks probably exceeds $5 billion and may very well exceed $10 billion. The public and private sectors are expending other large efforts on risk reduction programs, such as highway safety, energy related risks, dietary management, and many other life style risks. It should be possible to commission studies which place the risk reduction possibilities of various programs in perspective.

My final recommendation is for study of the risk decision process on a broader basis. Probably every interest group has its own perception of what the decision process should be on risk management. And many of these are worthy of careful analysis as a basis for synthesis of new approaches.

Many of my recommendations will require specific congressional amendments or laws to accomplish the maximum upgrading of science and fact. I would point out additionally, however, that much of the spirit of my recommendations could be accomplished by strong congressional oversight. Agencies should be encouraged and instructed to make greater use of risk assessment methodologies

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currently available and to articulate more clearly the decision process by which proposals are finally enacted.

In summary, my recommendations are that Congress should establish a science panel, upgrade the peer review system for agency fact finding and research programs, integrate peer review and the science panel in streamlined regulatory processes, and commission several studies to develop relative risk bench marks, to bring relative risk considerations to bear on the establishment of regulatory and national priorities, and utilize the oversight process to achieve greater short term utilization of risk assessment logic.

I hope it is clear to all of you why I have not specifically addressed alternatives to regulation in the management of risks. It is my feeling that what we regulate is most significant. If we can upgrade the fact basis available for defining risks and putting them into perspective, then the various mechanisms for regulating risk will be much more self evident.

MR. BOGEN: Thank you very much, Dr. Hoerger.

Let me move into the discussant phase of this seminar, and our first discussant is Dr. Radford, who I'm sure has some comments and questions for the speakers.

DR. RADFORD: Yes, indeed I do. I seem to be a representative of the academic community here today, but one who has been involved in public policy issues for many years now, and I find I disagree with a substantial amount of what's been said this morning. In the interest of trying to keep my remarks brief, I will pick out a few specific points.

Beginning with Dr. Hoerger's statements with regard to relative risks, we all know that there now exists in the literature a lot of assessments of risks, running from what is the risk of canoeing on whitewater, to getting in your family car driving to the supermarket. Here we're in the area of voluntary versus involuntary risk, and this is an improtant element in deciding whether risk is acceptable or not. The risks that one accepts voluntarily are very

different from the risks one would accept if they are imposed by someone else. I submit that we often do not have the choices that the free market economy implies. For example, one has little choice on what kind of food you can buy at the supermarket; the specific foods are largely prescribed by the food companies primarily, although we're beginning to get a little more flexibility into that situation. I'm very impatient with those who compare voluntary and involuntary risks and I usually object strongly to statements that I have seen so far in the literature. The calculus is simply not organized to look at involuntary risks relative to no risk at all.

To take one specific instance, the benzene case has been mentioned. In this case OSHA opted to go with a one part per million standard, not based strongly on scientific evidence, and this decision was struck down by the Supreme Court. I contrast that situation with the vinyl chloride case, where OSHA also opted for a one part per million occupational standard without a lot of scientific basis for it, approximately no more than existed in the case of benzene. That standard stuck. Apparently there was enough political steam behind that standard that OSHA was able to stand firm. Now the lesson in that case is the follow-up on economic impacts. Cost-benefit analyses had been carried out by very large consulting firms and had indicated that the cost of implementing a one part per million standard for vinyl chloride would be X million dollars or whatever number. (They ranged over a factor of at least 10.) Now that the standard has been in place for several years, somebody had the sense to go back and check what the actual costs had been to the industry, and it turned out that they were about one tenth of the lowest previous estimates. Furthermore, those capital costs have now been amortized, and as of about today, or maybe last year, the companies are making money by restricting the exposure of the worker to one part per million because they're containing the monomer vinyl chloride. They keep the product in the stream flow of production and they're making more money. So, we have then in fact, an economic benefit for having instituted a protective policy for the workers.

This story is indicative of what I consider to be the parlous state of cost-benefit analysis. There are many others who have spoken against this, and I recommend that you perhaps listen. Nick Ashford of MIT has been one who has been very active in pointing out that inadequacies of cost-benefit analysis, even if one can agree on how you're going to quantitate dollar values for risks and benefits. Lester Lave has correctly identified the difficulty of even doing that, so I don't have much use for cost-benefit analysis as it is usually applied.

Nor do I think that cost-effectiveness analysis is very helpful. Let's take the single most important public health problem in the United States today: the cigarette. In epidemiology we've become very very humble when we contemplate the situation with cigarettes, because as epidemiologists we've identified this as a major public health problem for 20 years at least. And yet, what's been done about it? Virtually nothing. Nevertheless, if I listen to what I'm hearing, until any agency of the Federal Government can identify that the risks of any agent are worse than the cigarette, one should not do anything about that agent because you've got to deal with cigarettes first. Now, that's obviously an overstatement, and I do intend to imply that that's really what the agencies do, but I'm saying if we waited to deal with only the big problems first, we'd wait forever. I say we've got to go with what evidence we've got. This idea has been an axiom, I believe, of the environmental movement since it started: strike where the iron's hot. And where the iron's hot is where the political pressure is. I don't have to tell this audience that politics plays an important role in any of these regulations.

What about the academic input and peer review? That question is tied in with something that Judge Markey said: "Who decides the acceptable risk?" He said, "Please don't give it to the courts," and I certainly echo what he said there. But then the question is, do you give this question to the scientists? I was introduced as being former chairman of the BEIR Committee, and I can assure that I am completely disenchanted with the idea of giving the question to the scientists. Who are they to make the decisions as to what should be an acceptable

risk? We have the classic example in the International Commission on Radiological Protection (ICRP)--which is a self-appointed, self-perpetuating group-making decisions which, in fact, EPA and the National Institute of Occupational Safety and Health are proposing to give regulatory force in the United States.

The United States has hitherto taken positions which have differed from the ICRP, I'm happy to say. But I think it is questionable whether, in fact, a self-appointed group of scientists are the ones that should be doing this. I echo what Judge Markey said: "Decisions such as this should be in the political domain." The representatives of the people have the responsibility of deciding what's an acceptable risk, not the scientists. Scientists are often the worst people to make these decisions. And despite my position in academe, I would be chary about peer review groups or the academic role in decision-making. Diogenes is still out looking. It is possible to buy scientists in academe about as well as you can buy expertise anywhere else; scientists are people too and have as many emotional and other factors that govern their opinions as anyone else. So, I don't think it is wise to look to the scientist to be the pure individual in the ivory tower.

I think that the whole scientific community has become politicized, and the BEIR Committee controversy is a classic example of just that. The linear-no threshold dose-response curve caused embarrassment to many people in various positions, not only in Government, but industry and among other groups, and therefore a determined effort was made to repeal it through the scientists. And maybe they've succeeded. Consider the saccharin case. The question was whether it was a significant carcinogen. Scientific evidence indicates that it is at most a very weak carcinogen. Let's get the facts straight if we're going to start talking about regulating a substance.

DR. HOERGER: I believe you were talking about risks, not potency.

DR. RADFORD: Well, I interpreted risks in terms of potency.

DR. HOERGER: Okay.

DR. RADFORD: The question about whether nitrosamine are a human carcinogen has not been settled. There is no evidence that nitrosamines are carcinogenic

in man, and I therefore take issue with Lester Lave's statement that they are a potent carcinogen. We've got to get these technical issues settled before we can start to regulate, and I certainly agree with many of the remarks that have been said on that.

I guess basically some of my concern stems from Judge Markey's statements implying that risk is fun. It's not fun for a coal miner to go into the mine every day and know that he may die either quickly or slowly, quickly because of a mine accident or slowly because of pneumoconiosis. It's no fun for a chemical worker not to know what material he's handling and to find out--maybe his widow will find out--that they were handling hazardous materials for many years.

The whole history of our inability to regulate risk hazards in the workplace is a blot on our escutcheon. I consider it a national scandal the way we tolerate the kinds of hazards that exist in the workplace. Many of the hazards that are said to exist for the general public are overstated, no question about it. The hazards of air pollutants, for example, have been overstated, but regulating air pollution was an early tempting target. Because people could see the black air they said, "We don't want black air." And so they figured out a way to get laws passed which, unfortunately, put the emphasis for regulation on abating health effects, which turned out to be very difficult to demonstrate. The point I'm getting at here is that in the technical realm we have great difficulty in finding a consensus that will allow the regulator to be able to build on a quantitative assessment of risk.

I think anyone who tries to put a heavy emphasis on cost-benefit or even cost-effectiveness is putting their emphasis in the wrong place. I believe that technology follows regulation in many cases, not necessarily all, but the possibility is there that if the regulations are put in properly, then it may well be that the control technology will follow and we can achieve the desired result with minimum economic dislocation.

I think it was Michael Baram who emphasized regulatory reform. I've been dealing with regulatory agencies off and on in various consultive capacities or on advisory committees for many years, and I think it's clear that efforts

to try to regulate on a piecemeal basis, as he emphasized, are doomed to failure. Take OSHA, for example, with X number of inspectors where X is very limited, how on an inspection basis can you ever really achieve the result of controlling hazardous conditions?

There is room for innovation, and I'd like to suggest one to give you an illustration. It happens that the Japanese have a very different system of regulating hazards in the workplace. It's an interesting footnote to history that this system was passed into law in Japan in part at the instigation of the MacArthur administration during the post-war period when the government was, in fact, under U.S. regulation. The MacArthur administration recommended that the Japanese government or the Japanese legislature pass laws that are now in force. In effect, what they do is put the burden of inspection and maintenance of safe working conditions locally in the plant. They detail one worker, usually full-time if it's a big plant, maybe more than one if it's an even bigger plant, paid by the company but responsible to the national government for monitoring compliance with regulations. This is a worker who knows every man by first name and who is responsible for collecting blood samples, if they are necessary, for collecting urine samples if necessary, or for collecting air samples. These men know the internal workings of the company. This system diffuses workplace inspection to a possible arrangement that can work. It is a historical fact that Japan has had relatively good industrial peace, not much worker dissatisfaction. In fact, their paternalistic system is considered one of the reasons why the Japanese are out-performing us, say, in the construction of automobiles.

I think there is plenty of room for innovation. Look to the academic community for help, but be careful. You may have someone who may not be as objective as you think. Maybe I'm not completely objective either, but at least I like to think my responsibility is to the public and not to anyone else.

MR. BOGEN: Perhaps one of the panelists would like to comment on that?

MR. BARAM: I want to comment on that. I've served on several committees of the National Academy of Sciences with scientists, and, naturally, I feel quite

humble on technical matters in their presence because I'm a lawyer trained in engineering, and have nowhere near their science or their knowledge of the stochastic approach taken to risks. Yet, my overwhelming impression is that Ed Radford is correct: scientists are not utopian individuals without any self interest. I found virtually every committee that I've been on to be composed of deeply entrenched personal interests, either academic theoretical interests, fiscal, or other types of interest. On the radioactive waste management Comittee of the National Academy of Science, for example, the resurfacing of the seabed disposal proposition comes up time and time again for more study from the same people who have entrenched interests in doing costly research on seabed disposal. Also problematic is the scientific presentation of risk. I often find it deficient, even in my ignorance of science, to hear an eminent scientist on the same committee talk about future seabed disposal as contributing only a minute fraction of additional radiation to the entire world's oceans. This is very misleading because it doesn't get to the distributional aspects, where that radiation would be concentrated, such as it is now off the California coast and a few other places. To present risk information in such a misleading, highly aggregated way, I find irresponsible. So I think the kinds of proposals that we've heard this morning for elitist, enclosed, science courts are not fully considered.

DR. HOERGER: Let me characterize it if I--

MR. BOGEN: Judge Markey.

JUDGE MARKEY: If I can just very quickly-- The value of discussants and questions is to correct speakers when they left a misimpression. I hope I didn't say risk was fun, although I've taken a few risks in my life which turned out to be a great deal of fun. But in any case, while risk might be fun, I think what I said or tried to say was that a riskless life so controlled and so guaranteed to ensure against all risk would be non-challenging, non-progressive, and no fun. I think that's true. I think generally we're pushing and leaning politically, sociologically, and every other way in that direction, and it scares the bejeebers out of me.

For 18 years as a general officer I made my soldiers and officers do things you wouldn't believe--right down to the details of what they ate, when they slept, whether they could put their arm on the canopy as they taxied the airplane. Why? Because the canopy might come down and cut it. And I would explain to them, "This ain't no democracy," this wing that I was commanding, "this is a dictatorship, and you're looking at the dictator." I happily, dutifully, importantly, necessarily enforced regulations right down to the length of the hair they could wear so it fit under the helmet. Why? Because I, representing the United States, owned that pilot, owned him, and if war came, we needed him in the cockpit, not in the hospital somewhere with a broken arm.

Now, query whether we are leaning in that direction so far that we will have a militaristic society in which, as I said, everything is ordered or forbidden. That's what I was getting at when I said a risk-free, a riskless society; a riskless life. It wouldn't be any fun at all.

MR. BOGEN: Dr. Hoerger.

DR. HOERGER: I'd like to clarify one point and that is on the science panel concept and the peer review concept. I think much of the problem that we have in the scientific community today is that scientists do try to get into the acceptability-of-risk type of area. I'd like to clarify that the purpose of the science panel concept is to focus on characterization of the risk. To illustrate, if an initial proposal is misleading on, say, the health significance of trace amounts of radiation, hopefully the peer challenge in the peer review process will correct that type of situation.

I think it is a little bit misleading also to characterize the science panel concept as a science court. To me, when we think of a science court we often think in terms of a yes/no type of decision: there is or is not to be guiltiness, pay damages, or something like that. I think when we're dealing with these risk things we're talking about a balancing of factors and a characterization of a material along a risk spectrum. So it's not a yes/no type of decision.

MR. BOGEN: I think Walter Hahn has some comments.

MR. MANN: Just a few, Ken, since I think we ought to give the audience more of a chance to participate.

A couple of differences between yesterday's session and today's seem to be emerging rather clearly. One of them is this separation or lack of integration of the scientific aspects with the value aspects. We have used words like "political" among others for one side of it. There clearly is an impression, probably stemming from the training that many of us had in our reductionist heritage and Cartesian outlook, and others that you can break out certain aspects of complex problems like this to find elements of truth or falseness or better or worse, and that things are able to be "determined" in some fashion. That same heritage also seems to bring us to the point where we think we can break off pieces of this problem and assign them to other people for action. Perhaps that is true in the case of the institutional aspects as the Judge has indicated. But in terms of thinking through the problem we find that it is a holistic or a systemic situation we are dealing with. The values may dominate in one case and the facts in another as Ed [Radford] has pointed out. We seem to keep reaching for a state where there are answers, that these can be determined, and that there are algorithms, or analytical procedures that we can go through that will make all of this clear. I think one speaker put it very well, "This is a messy thing." We don't seem to be facing up to that reality except for Mike Baram's paper. I think I saw a lot of people out there nodding as you were talking, Mike, that through participation, aggregation down to a simpler level, and integrating many of these things we can deal with large segments of this problem provided we don't get too "scientific" about them.

What is lacking for this participative, more integrative approach are institutional means. In the Executive Branch we find that the agencies are making individual separate decisions. Decisions are made in the absence of a consideration of what impact they will have on decisions coming out of other agencies. The so-called regulatory council, regulatory calendar and regulatory

budget activities do not address the problem of how the interagency problems are dealt with. And don't anyone think that I'm suggesting an interagency committee; I've been around Washington too long for that Rather, we need a device that functions like most of us would like to think an interagency committee could operate. There is a definite need of some kind of new institutional form. If that need could be met one has to take the next level of how does that type of function within Government act with the private sector. We haven't discussed very much about that particular aspect of risk assessment either.

Only a few speakers have mentioned the notion of thinking ahead with respect to preventing some of these regulatory issues from arising in the first place. The Congress has taken a number of steps, with the creation of the Office of Technology Assessment, with the creation of its Congressional Clearinghouse on the Future, with the activities on emerging issues in the Congressional Research Service, and with the call for a five-year outlook on science and technology in the National Science, Technology Policy, Organization and Priorities Act [P.L. 94-282]. It is my suggestion that if we in the Congress exercise the process of foresight under Rule 10 of the House and the informal procedures in the Senate, we can at least, perhaps, make the problems of risk assessment not get worse faster.

There is a whole set of other institutional roles that have not been discussed at this seminar. They are possibly things which Congress can do much more about than it can some of these technical things.

My last point is we haven't really discussed very much about how to deal with the problems of today in all its messiness. What can we just plain get together and do under conditions of uncertainty and in the absence of full knowledge? Mike's study, which I highly recommend, deals with this in part. I think we have to take many actions now parallel with taking some of these longer range, more appealing, and perhaps more worthwhile approaches that are not viable today.

MR. BOGEN: Perhaps we will go right to Vaughn Blankenship's comments and get to audience questioning.

DR. BLANKENSHIP: I've had about five different sets of comments, some that I had before I came here, some that came to mind as I listened

to different speakers. When I heard Dr. Radford a whole new set of comments entered my mind. I think the one that I would like to focus on. In fact, it's a theme that I hear in the comments of both Dr. Radford and Judge Markey, and, to some extent in the remarks of the other speakers. Each appears to debunk one particular institution in favor of another. They're saying, "Don't trust the courts," or "The courts can't do it," or "The Judges aren't up to it," or "are overworked." Then, in the case of Judge Markey, he opts for something he calls "the people or the political process." Dr. Radford, on the other hand, debunks science and scientists. He, not coming from the court system but from the academic community, says, "Don't trust the scientists. Trust the politicians, the politics."

Well, the difficulty is in my prior incarnation before I went to the National Science Foundation I taught politics and I studied the American political system. I've been here on the Hill for about five months on a fellowship program and, once a week, we have seminars in which people come in and talk to us about how Congress works. At least two of the speakers threw out the institutions that they represented and opted for this black box called politics and said, "Well, that's the one that will solve the problem." I'm suggesting that all of these institutions have major problems, from the point of view of workload, from the point of view of information, from the point of view of managing their business.

I think what we have here is a situation in which every single social institution is much less than perfect. The courts aren't perfect. The Congress isn't. Neither are the scientists. So what we really are talking about here is, working with much less than perfect institutions. How can we improve the ability of these institutions to manage the problem of risk and how can we improve the ability of these institutions to interact with each other?

Take the court system, for example. I know, because we at NSF have received a number of interesting research proposals from the American Bar Association and even from some state court systems, that some of the very interesting things happening in the judicial system centers around a series of questions about improving the training of lawyers and improving the ability of lawyers and the court systems to interact with technical information. At least in certain areas it's clear that the courts are going to be pulled into arbitrating in the area of technical regulation--if for no other reason than because we've produced so many lawyers in the last ten years.

So here is an area in which I think there are some very innovative thinking going on in the court system about handling, with all its imperfections, the kind of things that Judge Markey is talking about.

Similarly, I chink we could get into a long discussion about scientists and scientists' participation in decisionmaking. There had been a good deal of thought about that. I don't just think you throw it out.

I would just like to make one additional observation regarding one of the things that really wasn't mentioned here--it ties back into what I thought were some rather shocking statistics presented during yesterday's session. I'll tie it together this way: one of the alternatives, of course, is no regulation. I read a very passionate statement along this line in a couple of papers by Aaron Wildavski. He can certainly speak better for himself than I can speak for him, but he has written an intriguing paper called, "Richer is Safer." 2/ As I interpret it, the essence of that article is that there's a high correlation between wealth of the individual and how safe they are, how healthy they are. Those of you who were here yesterday saw these rather incredible morbidity

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2/ Wildavski, Aaron. Richer is Safer. The Public Interest, v. 60, Summer 1980: 23-39.

statistics on blacks, black males, migrant farm laborers, and others. There is poignancy in those statistics, and I thought of Aaron's paper when I saw them. I mean, one argument that you can make is that the issue is not so much a problem of trying to regulate, but rather maybe what we really have here is a problem in income distribution. That's another dimension.

MR. BOGEN: Perhaps our speakers will have brief responses, and we can go to the audience for questions.

JUDGE MARKEY: I just have one, very quickly. As Dr. Blankenship mentioned--and incidentally I worked with the National Science Foundation on the project--some folks are trying to get lawyers to learn something about scientists and about science and about their methods, their foibles and failures, and vice versa, because the courts are involved with technology in so many different kinds of cases, everything from fingerprints and voiceprints to the product liability cases and that sort of thing. And, as a matter of fact, in the longer version of my remarks given this morning, one of the things I suggested is that we train judges at the Judicial Center not to be scientists, because that would destroy them as judges in my view, but to train them about science so they can handle those kinds of cases. But that, from my book anyway, is entirely distinct from making the final decision on risk, which, as I say, is not our business, just as a cook shouldn't be the gardener and vice versa.

Can I hold the mike for one more second because I would like to respond to Professor Lave's point. I was intrigued by the notion of two budgets, one internal and one external. The immediate figure thrown was $10 billion for the external cost to be the maximum that they could impose on the private sector. I couldn't help but sit here, living in this town, and visualize the September 25th rush to dream up ways and means of imposing more of a burden than the $10 billion burden so as not to get cut back next year.

MR. BOGEN: Dr. Lave?

DR. LAVE: That one I'll leave alone. [Laughter] I have three quick points. The first one is exemplified by the historians. I'm told that the Emperor Justinian

believed that sodomy caused earthquakes. I understand they worry about that in San Francisco all the time. Having gone to college in Portland, Oregon, I remember that the Pacific Northwest was a very quiet, indeed, backward place. Since the late 1960s all sorts of people have migrated north along the coast, and you see the result. Mt. St. Helen's really did it.

First point: get your facts straight in all this. An awful lot of what has gone on under the guise of social regulation has gone in without having its facts straight at all. There are a number of cases where a regulatory agency went into its hearings and discovered they didn't know what they were talking about. That is embarrassing for society, I maintain, not just for the regulatory agency. We've got to stop that and get ourselves together.

The second point is the one that Mike Baram made that I think has to be emphasized even more. The formal regulatory mechanism in Washington can handle a tiny, tiny proportion of cases, maybe a millionth of one percent, literally. You cannot have enough regulators in Washington, enough inspectors, to handle the whole job. The solution has to come from nongovernmental decisions. I think that Mike was making that point. I think that probably even the mechanisms he was talking about, such as negotiation, can only handle a small number of cases. Most decisions have to be made automatically within the structure. How much safety do you build into a product? How much safety do you build into the workplace? Those are not even matters of negotiation. Those are simply design parameters that are in the heads of some engineers and some equipment manufacturers. The issue is that the right "stuff" has to be in their heads.

The third point is that one should not underestimate the complexity of risk and the regulation of risk in society. I don't want to join in casting aspersions on various institutions. I think there's enough of a problem of that in society anyway. One of the things that's clear is that we don't have any completely competent, completely neutral individuals wandering around in Federal judicial robes or in academia or anyplace else, and we have to get rid of that notion. But what we can look to in our society is that we have a series of

institutions that do very well at what they do. Any time a scientist starts telling me about what his or her goals are for society, I tend to tune out. I don't think scientists have any comparative advantage in telling me what it is they want society to do. I think that for whatever faults they have, that's exactly what politicians are elected to do. They change their minds very often. Look at the campaign. [Laughter] But that's okay, society changes its mind too, and politicians have to reflect, should reflect, what's going on in society. Insofar as they don't, they don't get elected anymore. What it is that the scientists are good for is trying to figure out the relevant facts. Don't ask them their opinions. Ask them what the facts are. Ask them what they don't know. They can do that relatively well.

What it is that only politicians can do, only the Congress can really do in our society, is to try and reflect social values and try to resolve value conflicts. The Congress is the only institution in our society that can do it. Now, lest I seem naive, I know that Congress has run away from that responsibility. When Congress votes on DES or nitrite or on whether to tolerate risks, they alienate half their constituency each time. Congress is going to have to face up to their unpopular responsibility. They're going to have to face up to it for nuclear power. They're going to have to face up to it for food and drugs. The time has gone where we can sit back and allow Congress to give agencies like OSHA a blank check in the form of ambiguous rules that give both the agency and the courts a hunting license. That's crazy. We've got to start giving the agencies some fairly concrete guidelines.

I was sketching out a set of frameworks. I have very strong views about which of those frameworks makes some sense and which don't. I'd be happy to tell you about them, but I don't have any comparative advantage in telling you what is the proper framework. I'll clarify it for the Congress and then I'll come in as a private citizen and lobby the Congress to use the framework that I like. If we clarify the framework and then get Congress to tell the agencies what it wants them to do and what areas have to be left for the private sector, then I think we're ahead.

MR. BOGEN: Any other remarks? Responses? Yes?

MR. ADAMS: Tom Adams, House Agricultural Committee. I'd like to say that I've been dealing first hand with the nitrite situation, second hand with the saccharin situation, and this question , the question of risk. They are very important on our committee at the present time. But one of the things that bothers me is that I've heard most of the panelists up here say what Congress is going to do, and I am glad to hear what you just had to say, Dr. Lave, because I don't know how many people in this room have attempted to suggest to a Congressman as a staff person what he should do, and to have him tell him right back, "Well, you know who you are and you know who I am."

But, most importantly, I would like for you to take the nitrite case and the saccharin case and examine them as to what Congress did with those two cases. On the question of saccharin, they referred it to the National Academy of Science and said, "Give us the answer." On the question of nitrites they referred it to the Universities Associated for Research and Education in Pathology, the pathology group, and said, "Give us the answer." Now, I'm sorry that you don't have that much appreciation for scientists, but maybe people really should have some appreciation for scientists and lawyers. I happen to be a retired military man too, and also a half-assed lawyer. [Laughter]

The other point I would like to make is that Congress is going to develop some type of a system by which they don't have to make the decision, and I think we've got to realize that. To say that we're going to constantly refer this back to Congress for a decision--I don't think it can work. You can't tie up Congress any more than you can tie up the courts.

However, I happen to work for Representative Bill Wampler (R-Va.), who is the ranking minority member on the House Agricultrural Committee, who has introduced a bill called the National Science Council Act of 1980 which would refer decisions, such as those that we've [i.e., the Congress has previously] worked

out in the saccharin case and in the nitrite case, to a proposed council. 3/ It closely but not totally parallels the idea that the American Industrial Health Council (AIHC) has proposed. 4/ We have had a tremendous amount of support for this, especially from the private sector and the scientific sector. And would like to have your opinion, Judge Markey, on this Science Council, not a court, the Science Council.

JUDGE MARKEY: Well, I think first of all, you're right if you talk about throwing all these things back to Congress. As I indicated, Congress is swamped--no question about that-- with many things, of which this is only one. That's why I suggested that Congress's own agency, the Office of Technology Assessment, be involved where an agency's assessment is being challenged technologically. A legal challenge goes to the courts; no problem. But when we've got a technical challenge, that I think, could be reviewed by Congress's own Office of Technology Assessment perhaps aided by outside scientists and so on. If they found that an agency assessment was a mistake, that there wasn't enough analysis done, it would go back to the agency. Congress is still out of it. That is, the individual congressmen are still out of it. If, on the other hand, an impasse is reached--the Office of Technology Assessment (OTA) says it's too high or too low, the agency insists that they were right the first time--now you've got a problem. Now, that focused inquiry on the risk of saccharin, let's say, goes to the Congress; just that one question at that time. Of course, there would be other questions, but they'd be very tightly focused down: Shall it be banned or not? Shall it be this or that? It would be a very focused inquiry.

But, let me return the question with a question. Why the council, why bypass OTA? I'm no lobbyist for OTA, but having set up the Office of Technology Assessment, isn't that a logical vehicle rather than a new council? I agree with

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3/ H.R. 638, 97th Cong., 1st Sess.; Jan. 5, 1981.

4/ AIHC Proposal for a Science Panel. New York, American Industrial Health Council, Inc., Mar. 26, 1980.

Professor Radford 100 percent that scientists are people and Diogenes is still looking. What a wonderful line

MR. ADAMS: That's the truth too. But, why not go to OTA? Because some people would think that OTA might be too political. [Laughter] In other words, they would want an independent science council. I'm not criticizing people coming out of OTA, except that they are just like the House Agriculture Committee in a way. They're organized in the same manner. Someone puts somebody on there, and the people have put him on there politically. Now, so the proposed science council would be a little bit more independent, I think.

DR. RADFORD: I'll make my remarks very brief. Since I lit the fires now, I'll try to bank them a little bit. I'm not saying that scientists are morally corrupt or anything like that. That's not true. As a matter of fact, as a group I find them as honest as anybody else, maybe a little more honest, but the point is that when we get into the realm, and I'm echoing what Lester Lave said, when you get them into the realm of making social decisions, they aren't any better. . . .

MR. ADAMS: We're not talking about social decisions. . . .

DR. RADFORD: Oh, yes you are.

MR. ADAMS: We're talking about whether there is a risk. That's all. And that's what I think the--what is it where the nitrites or the nitrite study conducted by Newborn, was it a balanced study or not?

DR. RADFORD: Yeah, O.K., that's a technical issue, but believe me, every time the Congress hands over to the National Academy of Sciences, say, give us a decision on saccharin or something like that--bang--it's in the political social realm. And, you know, the Academy, I'm sorry to say it, can get any kind of report out it wants depending on who they appoint to the committee.

MR. BOGEN: Could the questioners please stand up and identify themselves? Yes, back there?

MR. GOFF: I'm Mike Goff. I'm with the OTA. I read Judge Markey's after-dinner speech a year ago in which he said he hadn't consulted anybody in the OTA.

JUDGE MARKEY: I still haven't. [Laughter]

MR. GOFF: . . . Still haven't. But I want to put in a plug for the place I work. The first response of the Congress to the FDA's decision that saccharin was a carcinogen was to hand it to the OTA. And nine weeks later we said yeah, the FDA had acted responsibly given the nature of the way the tests were run, what we knew about science, and the results of that test, saccharine appeared to be a carcinogen. There was no disagreement about the science. That was then handed to the National Academy of Science. Again, there's no disagreement about the science. The National Academy said, too, that given what we know about testing, given what we know about carcinogenicity, saccharin is a carcinogen.

The Congress never objected, never said anything about the scientific decision. What they did was the risk-benefit decision, they and Coca Cola. [Laughter] If you remember, after the FDA announced its decision, when you went down to the local supermarket to buy your carton of TAB, there was a postage-paid postcard there saying, "Send this to your Congressman to say you really object to this."

Well, that guaranteed a lot of mail to the Congress. And Congress did do what Judge Markey said it does. It made the balance. The assessment was done. But what I'd like to ask Judge Markey is are there ever purely technical questions that come to a court where your review board would have a role? In your speech, sometimes I think risk assessment and acceptable risks get mixed up.

JUDGE MARKEY: I'm not sure I clearly understand the question, but what I was trying to say was that we unelected, politically unaccountable-for-life judges sitting in courts whose function it is to determine questions of law, in an entirely opposite approach from any scientific approach, have no business saying, in my view, that the public should or must--if the court says it, that's it--accept this risk, e.g., of one part per million, that that's all right, and that ten parts per million is too much. We aren't equipped, trained, or, in my view, authorized appropriately in that business.

Now, we do have in many cases, where there is testimony by experts, usually conflicting testimony, on whether or not a product was inherently unsafe the day it was made, whether the design was unsafe in product liability cases, and other

types of technological questions. But that isn't what I was talking about. I was talking about the courts saying the public should accept this risk, whatever it is. Very bad. After all, that's what the Congress would be doing under my suggestion, albeit advised by OTA as to the technology involved, if it's a technological fight. If it's a legal fight, there's no problem. We'll handle that.

MR. BOGEN: Yes, back there?

MR. RAIFFA: I'm Steve Raiffa with the Subcommittee on Crime with the House Judiciary Committee, so I come at this whole topic from the vantage point of the criminal law. I'd like some feedback from any of the panelists who want to address what possible role future Federal criminal law might play in those cases where there is a knowing concealment of some risk with regard to a specific product or business practice. I'm speaking here with reference to a bill sponsored by Congressman George Miller and John Conyers, H.R. 7040, which has been the subject of six hearings in the 96th Congress so far, which would do that, which would create an affirmative duty on the part of appropriate managers, as defined in the bill, within a company to disclose, just merely to disclose, the existence of what's defined as a serious danger, that is, one that could cause death or serious bodily injuries. It doesn't require that the product then not be manufactured or anything else, but merely that there be this affirmative duty to disclose to any appropriate Federal agency the existence of a potentially lethal risk, and makes it a felony for willful coverup or failure to disclose.

This grew out of such cases as the allegations surrounding the asbestos situation and others, and I was rather intrigued that the discussion both yesterday and today never brought in the possible role that the criminal law might play in deterring or at least dealing with what Professor Radford referred to briefly at the beginning of his remarks as this myth, if you will, that consumers are always in a position to make an informed decision with regard to whether with reference to specific products or business practices, they want to buy that particular product or not. I'm just curious whether any of the panelists have some feedback.

MR. BOGEN: I believe that this bill would also prohibit retaliatory discharge of employees.

MR. RAIFFA: That's right. There's a protection-of-"whistleblowers" provision that would make it a misdemeanor for anyone to retaliate against an employee making a report pursuant to the bill to an appropriate Federal regulatory agency.

MR. BOGEN: I think, Mike Baram.

MR. BARAM: I want to comment on the general proposition. I haven't seen the bill, but, in my experience, the threat of personal liability is a very important one to the corporate official and often prompts his greater concern about compliance with regulations and with general standards that are not agency rules, but which are standards of "reasonableness" imposed by common law, and other standards of criminal law. So the threat of personal liability is a very significant one, and would seem to overweigh regulation in its impacts based on my limited experience.

On the other hand, questions of proof are going to be very, very difficult. In the usual criminal kinds of cases, personal liability cases, you're dealing with the search for knowledge of deliberate misrepresentation by corporate officials. There have been recent cases involving a number of companies. I think FMC Corporation officials were recently brought to court because of their alleged misrepresentation of the discharges that were going into receiving waters. Finding deliberate misrepresentation is going to be quite difficult unless this bill makes some assumptions or works other reforms.

On the one hand, personal liability can be a powerful tool. On the other hand, I think it would be very difficult to carry out in practice. Attorney General Civiletti has recently come out with a Justice Department manual on white collar crime, and pollution, for example, is one of the categories. I haven't seen the manual yet, as its publication was just announced. We might want to take a look at it.

MR. BOGEN: I might point out before we go to some of our other speakers that seven or more of the recent pieces of environmental legislation have employee

protection provisions in them. If you're interested, we might pursue that. Dr. Radford.

DR. RADFORD: Yes, I'd just like to echo what Michael said. I think, in fact, especially for the Toxic Substances Control Act (TOSCA), that possibility is probably the most important thing that's happened. I think it's Section 8(e) which deals with the question of concealment of evidence of potential risk. I know from personal experience that this has shaken up the board rooms in major corporations because they suddenly realize that they are under a manadate by law to disclose information that might indicate health effects on workers. Now I agree with Michael that there may be occasions when it's difficult to implement this in a legal case. But in many cases now, the hazards are obvious. What OSHA is doing is looking at some of its possible regulatory court actions in terms of criminal actions. I know from personal experience that hazards are sometimes so egregious,and it is so obvious, that the company has ignored an imminent hazard and death has resulted, that OSHA is prepared to go the criminal route. I think it's only going to take about four or five cases--and maybe Judge Markey can indicate how likely they are to win or lose [laughter]--with senior executives of major corporations going to jail, and that will have more effect than all the regulations you can imagine.

MR. BOGEN: Dr. Woerger.

DR. HOERGER: I'd just like to comment that the operational problems with this type of statute are quite tremendous. I don't think that they're all imminent hazards that we're dealing with. There are degrees of subtleness in these signals. Do you make a positive type of warning for a single Ames test? I think that the thing that we're faced with is the fact that much of our health information is an evolutionary process. We have the Section 8(e) situation in TOSCA. There are provisions in the pesticide law [e.g., the Federal Federal Insecticide, Fungicide, and Rodenticide Act]. I think that to a degree we have in at least the chemicals and this type of product business considerable legislation that already accomplishes the [congressional risk management] intent. I

do have worries that if we go too far, we're going to create tremendous operational problems beyond just the burden of proof on the [question of] willfulness. What do you make the notification on? I would say that 99.9 percent of the corporate officials do want to get every bit of information on risk out there. The incentives are already there, but this clarification of what is a risk is still really the fundamental operational problem.

MR. BOGEN: Do you have any perspective on employees who might go public with internal information from a corporation and then get retaliated against? Do you have any experience or comments on that?

DR. HOERGER: I'm sure that there are instances of this. I guess it would be my observation that there are a fairly small number of instances where there has been retaliation. To my knowledge there haven't been many instances.

JUDGE MARKEY: Of course, if the bill were passed and widely known, there'd be less likelihood of that sort of thing, Ken, I suppose, because the information would have been disclosed anyway. The employee who was reporting it is behind the power curve. It's already out. I think the "60 Minutes" showing of dumping of chemicals, with reports from the man in charge of dumping the chemicals saying "I think this is terrible and it's injurious," and all that sort of thing, was one of the strongest influences on our picture here. The whole kepone picture looked bad as far as I could determine from the press coverage. You get back to what Mr. Baram was saying about nuisance and tort types of laws, the right to sue. The problem with that, of course, is that each individual person would have to sue on his own, which is great, as was mentioned earlier, for the lawyers.

We have 500,000 lawyers, half of them to write the gobbledegook in the law and the other half to try to figure out what it says. But the criminal aspect of it, while it does have difficulty of proof, we have to face up, I think, to the fact that here sits this man who is responsible for the bottom line on that corporate report at the end of the year, and he's looking at it, and he knows that if he exposes this, if he stops doing what's going on, the bottom line is going to show a loss and not a profit, and he could lose his job.

The temptations must be very strong to cover it up and rationalize it by saying that, "Well, I won't hurt anybody. I'll do this and that, but at the end of the year I'll come out looking all right and next year I'll clean it all up and it won't show." The temptations are rife, and, after all, the only thing criminal laws are directed against are the temptations and our propensity for falling victim to them. And, like the guy said, the thing that's wrong with resisting temptation is that it might not come again. [Laughter]

MR. FENSTERHEIM: I am Bob Fensterheim and OTA has been brought up a couple of times. I don't want OTA to dominate the questioning, but I work with Michael Goff. Let me try and rephrase the question he raised because we've been struggling with it for a while.

There's the AIHC proposal to deal with scientific issues, Wampler's bill is to deal with scientific issues. Judge Markey has made the statement that the courts are overburdened with having to deal with technical issues.

JUDGE MARKEY: Excuse me. Overburdened in general.

MR. FENSTERHEIM: Overburdened in general. Fine. My question, then, is are they burdened with having to deal with technical issues or do they for the technical issues defer to the agencies and go with their decision? If they do have to struggle with the technical decisions, then there may be a need for these scientific expert blue ribbon panels. But if it's not the actual technical decision--not the acceptable risk issue--but rather whether an Ames test is done properly, whether a bioassay was done properly, do the courts have to deal with that and would deferring to a blue ribbon panel reduce the burden on the courts?

JUDGE MARKEY: As I understand the proposal, and I don't want a "Bumpers" sticker on my car when I leave, part of the problem is that the courts are there, and so somebody says, "Hey, Congress isn't doing it. Nobody else is doing it. The executive isn't doing it. Let's get the courts to do it. They're handy. They give prompt decisions and it would be great if the courts would do it." That's happening everywhere, not just in the field of our interests here this

morning. I would like not to be thought of as pointing to the burden on the courts, the burden of work but in the longer paper, which of course was too long for this morning, I tried to point out I don't care if the courts had nothing else to do, if we didn't have a single case before us, I would still say we have no business making risk assessments for the people. That's not our business.

Now, I know what you're getting at, I think. The courts do defer by necessity to decisions of the agencies on, say whether an Ames test or a litmus test should be used or something else should be used to run a test, and that sort of thing. If it appears on the record that they did, in fact, conduct an Ames test, and if there's any question about that, the court might send it back. But we do not substitute our view on technology for that of the agency. If there's sufficient dust thrown up, we might say they didn't come up with enough evidence, but that's as far as we go now, and I'd like to see it stay that way. We have no business getting further into in it. We aren't trained for it.

MR. FENSTERHEIM: The AIHC group or the Wampler group or whatever blue ribbon panel, whether it be within NAS, really would not reduce the burden. What I'm reading from you is that judges say "we are not making technical decisions," and, therefore, that deferring to another group would not assist them.

JUDGE HARKEY: What I was saying was not that giving it to us we would reduce the burden. I'm saying don't give it to us because it would add to the burden. In other words, we already have 137,000 cases for 450 Judges. Now, think that out for a minute. Ask yourself, how is it possible for a Judge to give the careful, contemplative, considerate, thorough consideration to every one of those cases that they deserve? But we can get into hours of that.

What I tried to say was there are two reasons for not asking courts to assess risks: one because we're not trained and equipped to do it; second, if you add it to what we're doing now, when we're close to collapse and only by doing certain things have we avoided collapse--if you throw all that on top of us--we will collapse. The public will find out that our courts don't know how to do it, and our sanity will be in more trouble than it ever was.

MR. BOGEN: Yes, a follow-up?

MR. BARAM: For a variation on this theme, Judge Leventhal, just before his untimely death, said that he thought the role of the courts in dealing with matters involving considerable technical uncertainty was essentially one of "determining how matters were proven"--that the function of the court in such cases of judicial review was to determine how matters are proven. That can be construed procedurally. Did the agency follow all of its own regulations? Did it follow the statute? Did it follow prescribed scientific peer review procedures, et cetera?

On the other hand, that can be dealt with as a substantive kind of review function as well. The court may be dissatisfied that one of the steps in the process of proof did not properly consider competing, valid viewpoints within the scientific community. So I reject the notion that the courts should be spared the problem of reviewing how agencies have proven or disproven actionable risk or unreasonable risk. I think you'll find many diverse opinions in the courts, and a willingness on the part of the courts to assume that risk issues are really not that much different from those in an automobile accident case, that in both types of cases, we are basically concerned with how things are proven. Did the agency do a reasonable job, within its scientific expertise, on a best-efforts basis, of proving something? If so, then courts will generally defer to the agency findings.

JUDGE MARKEY: I agree thoroughly. We're doing that now, as I said in my remarks. The key is that those opposing the agency point out how it failed to follow its own procedures. The court wouldn't decide that on its own, without input from the apponents of the agency. So it is a procedural question, basically. The courts have been willing to do that and will continue to do it, I'm sure. But that's a different thing from saying, "We hold that a proper risk is so and so." A very big difference.

MR. BOGEN: I think we'll take two or three more questions from the audience. Back there?

DR. LAMB: I'm a professional consultant in occupational health. I'd like to pick up on the comment that Dr. Lave made in making the point that one has to have one's facts right. I find that in a lot of work that I have been doing the set-up comes that the agency receives a certain work product, a certain study, and decides on the basis of that study that it has to make a regulatory decision, and then often on an emergency basis the agency announces that decision without having released the original study upon which that decision was made.

We each in our area of work develop certain rules on how Government works. One of the rules I developed is that if an agency makes a regulation on the basis of a study before releasing the study, the study won't support the action taken. So, recognizing this, what I would like to suggest would be if the mechanism could be developed whereby the agency might make first a public announcement in the Federal Register or what have you saying, "We have received the following information and before we take our decision as to how to respond as regulators to this information, we would like to make that study and the background information open and allow a public comment period. Once the information and critique comes in from all sides, then we can deal with trying to develop the regulatory response."

I think this type of structure might fit in well with the type of concept that Dr. Hoerger suggested, but I think what's important is to be able to lay out first the scientific basis and get some agreement on that. One place where this has been tried and I think very successfully, people have referred to the vinyl chloride story. I would suggest that, looking at the DPCP experience, a problem developed there. The National Institute of Occupational Safety and Health worked together with developing the data base with the industry, with the union, and with the Government. A meeting was held in which all the information was reviewed. Things moved on. OSHA had made its regulations. It was one of the few regulations of OSHA that was not contested in the courts. And I think one of the bases for that agreement was because the scientists agreed in the first place what the basic science was and what it meant.

MR. BOGEN: Thanks for that comment. We have a final response. Yes?

DR. BLANKENSHIP: I wanted to come back just for a moment to one issue that was said earlier, because I think there's a need to put it in slightly different perspective. The question was raised over here about criminal liability, and in responding to this some of my colleagues here on the panel had what I would call a kind of simplistic notion as if there's a decisionmaker who sits down at one point in time and who looks at his profit and loss statement and says, "Well, gee, you know, I can sell more of these or I can kill so many people, and, you know, how do I balance that off?"

Now, some of the ambiguities of that kind of a law have already been alluded to, the difficulty of the information that's available, the difficulty of when it comes in, the difficulty of establishing cause and effect, and so on. But I still think that the problem is broader than that. Issues of environmental pollution very frequently involve more than one actor. They involve, say, state inspectors. They involve unions. They involve local communities which are concerned about a place being closed down. I simply want to stress this because this kind of simplistic notion of cause and effect, you know, that there's a thing that happens out there and you can pull out of a very complex social and economic structure one person who at one time sat in his office and said, "Here's my profit and loss statement, and I'm going to do this." I think that does a disservice both to that black box--I mean that black box is at least as complicated as the congressional black box--and it does a disservice in the public policy arena because it, I think, often directs attention to the wrong actors or it defines the problem in much too simplistic and narrow a view, even though sometimes it's very ideologically comfortable to think of it that way. It's always comfortable to think of the other guy as simplistic, e.g., he behaves solely according to a profit maximization motive. That's so simple to think about. From what I know about decisionmaking, that's just a gross oversimplification of the realities of these kinds of judgments, and that's what would concern me.

UNIDENTIFIED SPEAKER: Perhaps one final question. It would extend what you were saying that the problem of culpability versus prevention, and I was wondering if any of the panelists could extend this particularly into the area of nuclear power and this type of a workplace situation. My question is based on, perhaps, taking the kind of approach that I understand lawyers become very uncomfortable about, that the Civil Aeronautics Board in the investigation of any air accident, to find out everything that happened without worrying about exculpability. But what happened to extend this into the type of regulation again over power plants, nuclear power plants in particular, and I would close by the reason for my question is coming from a congressional office, out of [former] Virginia Congressman Fisher's office where we have VEPCO within our service area. It was very interesting to me, as I was talking with a safety engineer this very day about this type of thing, to have Ralph Nader--and I bring in the political side of it--gain national press by saying VEPCO had more reported instances, three times the reported instances, than any other utility had, and VEPCO is coming back saying that, "That's because we're doing what should be done, that's because we're reporting every single thing." Comments, please.

MR. BOGEN: Do you have any specific comments?

DR. MORGER: I can only agree that operationally I think some of the things you bring up are very real. At our company we have been involved heavily in toxicological testing, and so I sympathize with the statement that has often been made that the more toxicological testing you do on your own, the more likely you are to be stringently regulated. We're still going ahead and doing toxicology, but there's a real element of perseverence that you have to sort of keep struggling with there.

MR. BOGEN: I think rather than continuing with the questioning, I'd like to invite the audience to spend the next ten minutes or so introducing yourselves to one another and to come up and ask more specific questions of the panelists.

Thank you very much. I'd like to thank my CRS colleagues, Bob Civiak and Gail Marcus, for coordinating and arranging this CRS seminar with me.

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